Exponent®

Expert Report of Marion J. Fedoruk, MD, CIH, DABT, FACMT, FACOEM

in the matter of

Gilbert, et al. v. Lands' End, Inc. and Lands' End Outfitters, Inc.
Civil Action No. 3:19-cv-823-JDP

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Prepared for

Latham & Watkins, LLP
200 Clarendon Street
Boston, MA 02116

Prepared by

Marion J. Fedoruk, MD, CIH, DABT, FACMT, FACOEM Exponent, Inc.
15615 Alton Parkway, Suite 350
Irvine, CA 92618

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1.0 Summary of Opinions

Beginning on May 29, 2018, employees of Delta Airlines, Inc., ("Delta") were required to wear newly issued work uniforms ("Uniforms") manufactured by Lands' End, Inc. ("Lands' End"). According to the operative complaint in the matter of *Gilbert, et al. v. Lands' End, Inc., et al.*, since the introduction of those Uniforms, Plaintiffs have reported various respiratory, skin, sensory, neurological, and generalized symptoms that they attribute to "excessive allergen and sensitizing properties" in the Uniforms. In particular, Plaintiffs claim that their reported symptoms are due to levels of chromium, antimony, mercury, formaldehyde, fluorine, bromine, and other chemicals in the Uniforms that are in excess of industry safety standards for garments.

I have been asked to evaluate, based on standard scientific and medical principles of occupational and environmental medicine and medical toxicology, whether Plaintiffs' experts in this matter have established, to a reasonable degree of scientific and medical certainty, that the claimed exposures can result in the reported health injuries (i.e., general causation), and that the claimed exposures resulted in individual Plaintiffs' reported health injuries (i.e., specific causation).

Plaintiffs' experts in this matter, Dr. Michael Freeman, Dr. Pamela Scheinman, and Dr. Fred Apple, offer various opinions relating to general and specific causation issues. As a basis for their opinions, Plaintiffs' experts rely in part on laboratory test results for selected Uniforms, partial medical records and clinical test results for selected Plaintiffs, and Plaintiffs' self-reported questionnaire responses.

Based on my review of the available laboratory test results for the Uniforms, a subset of Plaintiffs' medical records, Plaintiffs' experts' reports, deposition testimony from fact and expert witnesses, and the scientific and medical literature cited in my report, and taking into consideration standard methodological principles of medicine and toxicology, my opinions are as follows:

- Plaintiffs' experts' opinions are not consistent with basic principles of toxicology and medical causation, including dose-response and exposure assessment.

- Plaintiffs' experts have not followed standard methods of evaluating general causation and specific causation.

- Plaintiffs' experts have not established that the claimed exposures to chemicals in the Uniforms can result in the reported health injuries in general (i.e., general causation), or that the claimed exposures resulted in the reported health injuries in any specific Plaintiff (i.e., specific causation).

I begin my report by summarizing general principles of medical causation and toxicology, and the differences between protective regulatory exposure standards and exposures sufficient to cause toxic health effects. I then address overarching issues raised by all three of Plaintiffs' health experts in their reports and depositions, followed by responses to individual opinions and statements made by Dr. Freeman, Dr. Scheinman, and Dr. Apple.

My opinions in this report are expressed to a reasonable degree of scientific and medical probability based on the information currently available to me. I reserve the right to supplement this report and to expand or modify opinions based on my review of additional material as it becomes available.

2.0 Qualifications

I am a licensed medical doctor, practicing in the fields of occupational and environmental medicine, medical toxicology, and industrial hygiene. I received my medical degree with Distinction from the University of Alberta, Edmonton, Canada, in 1978. I performed postgraduate medical training through McGill University, Montréal, and my residency in Occupational Medicine at University of California Irvine from 1981 to 1983.

I hold a primary board certification by the American Board of Preventive Medicine in Occupational Medicine. This is the medical specialty within the profession of Preventive Medicine that is focused on the effects of workplace and environmental exposures to chemical, physical, and biological agents. Physicians specializing in this area are required to have knowledge of clinical medicine, toxicology, epidemiology, biometry (biostatistics), and population health. I also hold a subspecialty certification in Medical Toxicology from the American Board of Preventive Medicine. Medical Toxicology is a medical subspecialty focusing on the diagnosis, management and prevention of poisoning and other adverse health effects due to medications, occupational and environmental toxins, and biological agents. The Medical Toxicology subspecialty board is sponsored by three primary medical boards: Emergency Medicine, Pediatrics, and Preventive Medicine. The board certification credentialing process involves a common examination for all diplomates, regardless of their primary medical specialty. Fewer than fifty physicians in the United States hold board certification in both Occupational Medicine and Medical Toxicology. Additionally, I am board-certified as a toxicologist by the American Board of Toxicology, a not-for-profit independent toxicology board established in 1979 that provides certification to scientists, who mostly hold doctoral degrees, as well as to clinicians who are engaged in the practice of toxicology.

The National Research Council's Committee on Science, Technology, Law, Policy, and Global Affairs' current edition of the *Reference Manual on Scientific Evidence* (NRC, 2011) identifies the board certification credentials that are recognized for "Expert Qualifications" for toxicologists. Namely, board certification is achieved by education, training, experience, and examination. In the chapter entitled "Reference Guide to Toxicology," three board certifications are listed that qualify for toxicology expert qualification: subspecialty certification in medical toxicology, board certification by the American Board of Toxicology, and board certification in occupational medicine by the American Board of Preventive Medicine. I hold all three of these board certifications. I also hold memberships in professional societies identified by the NRC as being related to toxicology, including the Society of Toxicology, American College of Medical Toxicology, and the American Academy of Clinical Toxicologists.

I hold a board certification in industrial hygiene from the American Board of Industrial Hygiene and am a Certified Industrial Hygienist with a specialty focus in toxicology. The discipline of

industrial hygiene deals with the assessment of workplace and environmental hazards, and measures to control such hazards. As an industrial hygienist, I have conducted exposure assessments and assessed whether various environments pose a health threat to workers or the public. I have expertise in the use of environmental exposure data to assess human exposure and ascertain potential doses that an individual might receive from different environments. Moreover, given my experience in toxicology, including medical toxicology, I have special expertise in evaluating the human health impact of such exposures. I believe that I am the only physician in the United States who holds board certification in occupational medicine, medical toxicology, and industrial hygiene—the fields that deal with both measuring chemical exposures and understanding the human health effects of such exposures.

I have been elected a Fellow of the American College of Medical Toxicology (FACMT). This recognition is awarded by the American College of Medical Toxicology (the specialty society that represents the nation's medical toxicologists) to medical toxicologists who meet the highest standing in their field. I also have been designated as a Fellow by the American College of Occupational and Environmental Medicine, an award that is given to College members in recognition of their training, accomplishments, and experience in occupational medicine.

In my professional career, I have consulted for both industry and governments in a wide range of occupational, environmental, health, and toxicological issues with reference to chemical exposures. I have also been involved since the 1980s in consulting activities related to chemical hazards, including measuring occupational and environmental exposures, conducting risk assessments of workplace and environmental exposures, designing and implementing medical surveillance programs, and developing worker and environmental communication programs.

At present, I am employed as a Principal Scientist for Exponent in the Center for Health Sciences, where I provide consultative services in toxicology-related matters, including forensic analysis. I am also employed by the University of California, Irvine (UCI) at the Center for Occupational and Environmental Health (COEH). The COEH was established within the University of California to train occupational health scientists and professionals, conduct research on occupational and environmental health issues, and provide services to the public, employers, and workers. I hold the title of Clinical Professor of Medicine in the Department of Medicine. I am also the acting Medical Director of the UCI COEH occupational and environmental medicine specialty clinic. In my role at UCI, I am active in providing clinical toxicology services and evaluating and treating persons exposed to toxins in the workplace, at home, and from the environment. UCI COEH has a residency program and I am active in training physicians to become specialists in this field.

In addition, I have conducted studies and published articles in the areas of occupational and environmental medicine, and written chapters in several books, including the World Health Organization's Encyclopedia of Occupational Safety and Health, and the Encyclopedia of

Toxicology. I am a recipient of the Merit in Authorship Award from the American College of Occupational and Environmental Medicine, and the Jean Spencer Felton Award for Excellence in Scientific Writing from the Western Occupational and Environmental Medical Association.

Exponent is compensated in this matter at my standard billing rate of $600 per hour.

My current *curriculum vitae* and testimony list are included as Appendix A.

3.0 Principal Opinions

3.1 Assessment of medical causation involves a standard, well-established methodology based on fundamental principles of toxicology and related scientific and medical disciplines.

The methodology for determining whether an individual developed a health problem from exposure to a specific agent (i.e., medical causation) involves several inherently individualized steps that are described in the National Research Council's *Reference Manual on Scientific Evidence* (NRC, 2011) and summarized below. This methodology provides a standard, generally accepted framework with which to evaluate the opinions of Drs. Freeman, Scheinman, and Apple with respect to the Uniforms and Plaintiffs' reported health conditions.

3.1.1 Define the disease or medical condition at issue.

A critical step in determining whether an individual has developed a health problem from an occupational or environmental exposure is to define the nature of the claimed medical condition or disease at issue. The process for defining the disease or medical condition at issue can involve several different approaches, depending upon the nature of the claimed condition and the availability of medical test information. A review of all of the individual's relevant medical records may be sufficient to establish the nature of the claimed medical condition. Persons with serious medical conditions such as cancer frequently have undergone comprehensive medical testing, in part to establish such a diagnosis, and their medical records may provide detailed medical data including a medical history, physical examination findings, laboratory test data, pathology reports, imaging studies, and other diagnostic study findings. In such cases, the nature of the claimed medical condition can be readily defined by reviewing the person's medical records.

However, medical records may not provide sufficient information to evaluate many health complaints. For some conditions, the individual may have received only symptomatic treatment and may not have completed planned diagnostic testing as part of a medical work-up. Symptoms are often non-specific and can be similar for underlying conditions with distinct etiologies.

The evaluation of health claims that are largely based upon self-reporting of symptoms is especially problematic. The same symptom can often have multiple medical causes, and many or most of these may be unrelated to the diseases associated with the claimed exposure. For example, rash is one of the conditions claimed to be associated with the alleged exposures at issue in this matter. However, attributing a rash to any specific medical cause is problematic because rash is a symptom of a wide array of medical disorders, such as atopic dermatitis,

cercarial dermatitis, contact dermatitis, drug eruption, eczema, heat rash, intertrigo, lichen planus, miliaria rubra, pityriasis rosea, psoriasis, rosacea, shingles, tinea corporis, and viral exanthem (Mayo Clinic, 2019; MedlinePlus, 2021). Several of the Plaintiffs' health complaints, such as rash, fatigue, skin irritation, itchiness, hives, headaches, coughing, and breathing difficulties, represent non-specific symptoms and/or physical findings that could be due to virtually innumerable medical causes.

To reliably evaluate a health complaint that is largely based on self-reporting of symptoms, or for which limited medical testing has been performed, it is usually necessary for the individual to undergo further medical testing to determine the underlying disease or condition responsible for the symptom. For example, if a person claims to have shortness of breath, which can be due to several diseases such as certain cardiac and pulmonary conditions, or simply being deconditioned, medical tests such as a graded exercise study can be performed to determine the underlying cause of the symptom.

3.1.2 Define the exposure at issue.

Another critical step in determining whether an individual has developed a health problem caused by receiving doses of a certain agent or agents is to define the exposure at issue (i.e., what agents are claimed as being responsible for causing the condition). The exposure circumstances at issue must be examined, since different exposure circumstances can result in substantially different exposure potential and related health outcomes. For example, factors that must be considered include the route (e.g., oral, dermal, or inhalation), the magnitude (i.e., the concentration of the chemical in media such as soil or air), the duration, the frequency, and the timing of exposure. Some agents produce toxic effects that are route-specific; for example, a given agent may be toxic by inhalation but not ingestion.

It is important that the exposure at issue be clearly defined and, where possible, quantified in terms of magnitude, duration, frequency, and timing. Of note, evaluating only the timing of exposure—in particular, whether it preceded the health outcome at issue—is insufficient to establish medical causation. Simply because a health condition occurs after an exposure does not mean that it was caused by the exposure (Grouse 2016). Instead, all of the characteristics of the exposure at issue should be compared with exposure characteristics measured in human epidemiological, toxicological, and other studies involving the same or similar compounds to ascertain whether such exposures have been established or could reasonably be expected to produce the claimed health problems (i.e., whether general causation has been demonstrated for a certain level and route of exposure).

A critical consideration when making such comparisons is whether the exposure at issue exceeds known thresholds for causation of specific health effects. Many chemicals, including the chemicals of concern in this matter, have known lowest-observed-adverse-effect levels

(LOAELs) and/or no-observed-adverse-effect levels (NOAELs) for various health outcomes, as summarized by the Agency for Toxic Substances and Disease Registry (ATSDR, 2021) and the U.S. Environmental Protection Agency (USEPA, 2021), among other health and regulatory agencies. The identification of LOAELs and NOAELs by these agencies is consistent with the notion that for every chemical (or mixture of chemicals), there is a level of exposure below which no adverse health effect is anticipated. Thus, exposure to an agent, even one with known toxic effects, in and of itself does not constitute a harm. Rather, that exposure must exceed some threshold—which may or may not be well defined based on the available scientific evidence—to be capable of causing an adverse health effect. In individuals with underlying allergic sensitization to a substance, allergic reactions—but not all reactions—can occur at lower exposure levels or doses than seen in the general, non-sensitized population.

3.1.3 Assess general causation.

General causation refers to the process of determining whether the claimed exposure is capable of causing the disease of concern at the specified exposure magnitude, duration, frequency timing, and route. The determination of general causation involves an examination of epidemiological and toxicological study data. Epidemiology is the science that investigates the determinants of disease in a population, such as genetic, dietary, lifestyle, occupational, or environmental risk factors. Epidemiology can address whether a specific exposure is capable of causing a disease (i.e., general causation), but not whether it actually did cause a disease in any particular individual (i.e., specific causation).

Toxicological data provide information regarding the toxicity potential of many agents, and an understanding of the mechanism of action (i.e., the process by which a certain toxic effect occurs). Toxicological data can be provided from human experimental studies, clinical trials, and animal toxicology studies. Toxicological data can provide information complementary to epidemiology in part by providing a framework to assess the biological plausibility of an epidemiological finding. The overall weight of epidemiological data can be synthesized along with toxicological data by using the framework proposed by Sir Austin Bradford Hill (1965) to evaluate the overall weight of evidence for a general causal relationship.

If general causation is not established—that is, if a given exposure at any level has not been shown to cause a given health outcome—then specific causation in an individual person, by definition, also cannot be established. If, however, general causation has been established under certain exposure scenarios, then the specific circumstances at issue must be considered to determine whether general causation applies to the matter at hand.

3.1.4 Assess specific causation.

The next step in evaluating whether an individual's health condition was caused by a given exposure is referred to as specific causation. The process of determining whether specific causation occurred in a given individual can be performed only after general causation has been established between a particular exposure and a particular health outcome.

The steps that should be followed for determining specific causation are discussed in the *Reference Manual on Scientific Evidence* (NRC, 2011). In making such a determination, several important factors must be considered. An essential step in establishing specific causation is demonstrating that the dose that the person actually received has been established by the general causation analysis to be sufficient to cause the disease (NRC, 2011). The term "dose" refers to the total quantity of a substance that is absorbed by an exposed person or received to the relevant target tissues. All chemical agents have potential for harm, depending upon the dose that a person receives; in other words, the dose makes the poison. Thus, quantifying the dose that a person received is a critical factor in determining causation.

As described by NRC (2011), the process of exposure assessment aims to answer the question of whether an individual was exposed to the substance, and if so, whether the exposure occurred in a manner that can result in absorption into the body—that is, whether the exposure resulted in a biological dose. Factors that should be considered with respect to dose include the route, magnitude, duration, frequency, and timing of the exposure. Other aspects of dose that may be evaluated are whether other factors were present that can affect the distribution of the substance within the body; what is known about how human metabolism alters the toxic effects of the substance; and how the substance is excreted, including how excretion affects the substance's toxicity (NRC, 2011).

Besides dose, other important factors to assess in specific causation include the latency between exposure and disease onset (e.g., whether the toxic effect is acute or chronic), and the potential toxic impact of the substance on each specific health condition at issue. For example, lead is recognized to cause anemia as a result of its effect on disturbing heme synthesis. In healthy adults, anemia generally is not seen at lead doses that produce blood lead levels below 30 µg/dL. Lower blood lead levels currently seen in general populations at this time do not affect heme synthesis to a degree that would result in anemia. Thus, to establish that lead was a cause of a person's anemia would require establishing, on a person-by-person basis, that the dose received was sufficient to increase blood lead levels above the effect threshold.

3.1.5 Assess alternative causation.

A final essential element in a disease causation analysis is exclusion of alternative causes of the health outcome in the individual in question. This step can also be considered to be part of a

specific causation assessment. Exclusion of alternative causes requires an understanding of the established risk factors for a given disease, as well as familiarity with each person's demographic, medical, behavioral, genetic, occupational, and other potentially relevant characteristics (NRC, 2011). In the case of a chemical exposure, it also requires evaluating potential sources of the chemical other than the alleged source at issue to the extent possible. As stated in the *Reference Manual on Scientific Evidence* (NRC, 2011; footnotes omitted):

> Eliminating other known and competing causes increases the probability that a given individual's disease was caused by exposure to the agent. In a differential etiology, an expert first determines other known causes of the disease in question and then attempts to ascertain whether those competing causes can be "ruled out" as a cause of plaintiff's disease [such as genetics]. Similarly, an expert attempting to determine whether an individual's emphysema was caused by occupational chemical exposure would inquire whether the individual was a smoker. By ruling out (or ruling in) the possibility of other causes, the probability that a given agent was the cause of an individual's disease can be refined. Differential etiologies are most critical when the agent at issue is relatively weak and is not responsible for a large proportion of the disease in question.

3.2 Regulatory and some industry standards are set conservatively to protect public health, and are not thresholds for causation.

Regulatory agencies' and industry groups' health-based exposure limits and recommendations cannot be used as a basis for conclusions regarding health injury or causation. Exposure limits and guidelines are set by governments and agencies charged with protecting public health with an adequate margin of safety based on conservative guidelines, often relying on extrapolation from studies of high exposure levels to low exposure levels, and/or from studies of animals to humans. These extrapolations involve conservative assumptions and the inclusion of safety/uncertainty factors that are intended to guard against harm to human health in general, including sensitive subgroups.

In the derivation of health-based exposure standards for toxic substances, regulatory agencies apply specific uncertainty factors intended to account for 1) uncertainty in extrapolating from a lowest observed adverse effect level rather than a no observed adverse effect level; 2) uncertainty in extrapolating animal data to humans; 3) variation in susceptibility among members of the human population; 4) uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure; and 5) uncertainty associated with extrapolation when the scientific database is incomplete (USEPA, 2002a; ATSDR, 2018). Such uncertainties also apply to industry standards such as OEKO-TEX® Standard 100, a product label and certification

system developed by the International Association for Research and Testing in the Field of Textile and Leather Ecology to test for toxic substances in textiles and ensure that their levels are "harmless for human health," taking into account "numerous regulated and non-regulated substances" (OEKO-TEX®, 2021).

Due to this considerable uncertainty and the conservative, protective nature of regulatory and some industry standards, it is not scientifically appropriate to use such values to determine whether a person has developed an illness or is at significantly increased risk of developing an illness. The Federal *Reference Manual on Scientific Evidence* specifically states that regulatory standards are not intended to be used for determining causation in the context of litigation (NRC, 2011):

> Particularly problematic are generalizations made in personal injury litigation from regulatory positions. Regulatory standards are set for purposes far different than determining the preponderance of evidence in a toxic tort case. For example, if regulatory standards are discussed in toxic tort cases to provide a reference point for assessing exposure levels, it must be recognized that there is a great deal of variability in the extent of evidence required to support different regulations … In addition, regulatory standards traditionally include protective factors to reasonably ensure that susceptible individuals are not put at risk. Furthermore, standards often are based on the risk that results from lifetime exposure. Accordingly, the mere fact that an individual has been exposed to a level above a standard does not necessarily mean that an adverse effect has occurred.

Thus, regulatory and some industry standard exposure levels are often set to demarcate points below which no harm to human health is anticipated, but not thresholds above which adverse health effects will necessarily occur.

3.3 Overarching issues pertaining to the opinions of Dr. Freeman, Dr. Scheinman, and Dr. Apple

In the following six subsections, I address key issues that are shared in common across all three Plaintiffs' health experts. These include their failure to account for exposure dose and other exposure characteristics, such as route and chemical form; their reliance on incomplete, unvalidated, and insufficient information on a small, selected subgroup of Plaintiffs to make generalized causal determinations for all Plaintiffs; their failure to account for limitations of the protocols and results of laboratory tests performed on Uniform items; and their misinterpretation of textile garment standards, both as they are applied to the assessment of laboratory test results and as they pertain to evaluation of exposure levels that are sufficient to cause adverse health effects.

3.3.1 Plaintiffs' experts identify no valid scientific evidence to establish general causation, i.e., to demonstrate that exposure to the chemicals at levels measured in the Uniforms, via the claimed exposure routes, can cause the claimed health effects.

Plaintiffs' experts variously cite selected references to support their statements that chemicals identified in the Uniforms are known to cause non-specific health symptoms and other health effects. Specific sources cited by Dr. Freeman are discussed in section 3.4.2, and those cited by Dr. Scheinman are discussed in sections 3.5.3 and 3.5.5. Sources cited by Dr. Apple consist of general toxicology textbooks (addressed in section 3.1) and general review articles and reports. None of these documents provide scientific evidence showing statistical associations, much less causal connections, between any adverse human health effects and dermal or inhalation exposure to the chemicals of concern at the levels measured in the Uniforms. (With respect to some types of skin hypersensitivity reactions, positive skin patch test results, accompanied by supportive clinical data, can provide strong evidence that a tested agent is causally responsible. In these instances, thorough assessment of specific causation is necessary based on individual-specific exposure history, medical history, and potential alternative causes.)

As discussed below, only one of the studies cited by Dr. Freeman is an epidemiological study that estimates an exposure-outcome association (McNeely et al., 2018), albeit based on methodologically highly flawed data that most likely yielded biased results. Neither Dr. Scheinman nor Dr. Apple cites any epidemiological studies of the exposures and health conditions at issue. Instead, Dr. Scheinman cites a review that describes case reports that have little bearing on the present matter (Yu et al., 2018), and articles that do not pertain to the exposures at issue (Mathias, 1989; Meyer et al., 2000; Turner et al., 2007; Leonard and Guttman-Yassky, 2019). Dr. Apple cites reviews that do not address health effects at all (Matsui, 2006), do not address the health effects at issue (Leso et al., 2020), or do not report health effects associated with comparable exposure circumstances and levels (ATSDR, 2003; Bakand et al., 2012).

Thus, Plaintiffs' experts have failed to identify even a valid statistical association between the exposures and the health outcomes claimed in this matter. Without scientific evidence of such an association, Plaintiffs' experts lack any scientific basis on which to claim general causation.

3.3.2 Plaintiffs' experts' specific causation analyses are scientifically and medically invalid because they do not account for exposure dose and other exposure characteristics, nor do they exclude alternative causes.

In the absence of established general causation, evaluation of specific causation is irrelevant; if exposure to an agent is not known to be capable of causing a particular health outcome in general, then it cannot be determined to have caused that health outcome in a specific person

(NRC, 2011). Nevertheless, even if general causation had been established between the claimed exposures and the Plaintiffs' various health complaints, Plaintiffs' experts Dr. Freeman, Dr. Scheinman, and Dr. Apple have failed to establish that any individual Plaintiffs were exposed to specific chemicals at doses sufficient to cause the claimed health conditions. Establishing specific causation would require examining each individual person's exposure circumstances and medical history, which Plaintiffs' experts have not done. Instead, they inappropriately generalize partial data on exposures and health outcomes from a small number of individuals to the entire population of Plaintiffs. Plaintiffs' experts have also failed to exclude alternative causes of the claimed symptoms.

As discussed in section 3.1.4, a fundamental principle of toxicology is that "the dose makes the poison." For any individual person and each specific chemical of concern, the magnitude, duration, frequency, timing, and route of exposure should be considered to determine the biological dose, if any, that is likely to have entered that person's body. The dose and other exposure characteristics can then be compared with exposure circumstances from human epidemiological, toxicological, and other studies to ascertain whether such exposures or doses have been established or could reasonably be expected to cause the health effects at issue. Moreover, even for persons with underlying sensitization to a given agent, medical records and supporting clinical information are required to whether reported skin complaints are due to sensitization or even irritation. The prevalence of contact allergy to any given substance is estimated at approximately 11–15% (for nickel) or lower (for other specific agents) (Diepgen et al., 2016; Alinaghi et al., 2019).

None of the Plaintiffs' experts, however, have estimated the chemical doses received by Plaintiffs or made comparisons with exposures or doses shown in epidemiological or toxicological studies to be associated (if at all) with the claimed symptoms. Instead, they appear to assume that the mere presence of a chemical or any exceedance of an OEKO-TEX® Standard, as detected by laboratory testing, equates to harm for all Plaintiffs, regardless of how the measured level compares with levels shown to cause adverse health outcomes. As explained in section 3.2, however, an exceedance of a regulatory standard or industry guideline is not equivalent to crossing a threshold above which an exposure is anticipated to cause a health effect. Therefore, test results showing chemical levels above such standards or guidelines cannot necessarily be interpreted as an indication of increased disease risk.

For instance, Dr. Freeman writes that "formaldehyde levels in some of the new Delta uniform items exceeded the OEKO-TEX limit values (LV) and, in one case, was more than 10 times the LV." He goes on to state, "Exposure to formaldehyde can irritate the skin, throat, lungs, and eyes. Formaldehyde is a carcinogen." However, he draws no comparison between the levels of formaldehyde shown to cause these outcomes in humans based on epidemiological or toxicological studies (primarily via inhalation exposure), and either the levels of formaldehyde detected in the Uniforms or the doses that would be expected to be inhaled or dermally absorbed

by employees wearing the Uniforms. Likewise, Dr. Freeman states that antimony was detected in Uniform items at levels that were 2.1 to 4.9 times the OEKO-TEX® limit values, and that antimony "can be harmful to the eyes and skin. Antimony can also cause problems with the lungs, heart, and stomach." Yet, he fails to specify the levels and routes of antimony exposure shown in epidemiological or toxicological studies to cause these health problems in humans, and he has not established that the levels detected in the Uniforms or doses anticipated to be absorbed by Plaintiffs were comparable to those causal levels. The same shortcomings apply to Dr. Freeman's conclusions regarding other chemicals of concern in this matter.

Dr. Scheinman also appears to implicitly assume that test results exceeding the OEKO-TEX® standards signify exposure levels that are sufficient to cause adverse health outcomes. For instance, she states: "Formaldehyde is a known irritant and allergen. Strict standards of formaldehyde release from clothing would be at levels <75 ppm. A number of the Tex Test formaldehyde results exceeded this level." Here and elsewhere in her report, however, Dr. Scheinman fails to establish a connection between the levels of chemicals detected in Uniform items—or, more appropriately, doses that would be absorbed by employees wearing those garments—and levels that have been shown in epidemiological or toxicological studies to be sufficient to cause adverse health effects in humans.

Dr. Apple's conclusions are similarly vague regarding dose. He describes, for example, certain laboratory test results as showing "extremely high levels of Chromium in tested garments of a flight attendant"; "extremely high levels of Fluorine and high levels of Bromine in tested garments of a flight attendant"; and "elevated levels of Antimony, Barium, Chromium and Nickel in tested garments of a gate agent"—yet he does not cite any scientific evidence documenting that the detected chemical levels in Uniform items, or the estimated doses of those chemicals absorbed by employees wearing those garments, have been shown in epidemiological or toxicological studies to cause any of the symptoms claimed by Plaintiffs.

The presence of chromium is not unexpected in garments; therefore, positive test results for chromium and other metals, without proper consideration of dose, cannot be interpreted as posing a health risk. For instance, a sample of 78 commercial nylon, wool, and silk textile products (106 samples) purchased from various online and retail stores in Japan found that chromium was detected in 66 samples, including at levels above 1,000 ppm in 49 samples and levels above 10,000 ppm in five samples, yet the authors found that after the fabrics were subjected to metals extraction with acidic or alkaline sweat, the measured levels of chromium (and cobalt) were "not likely to cause contact dermatitis at concentrations eluted into the artificial sweat" (Kawakami et al., 2020).

Besides ignoring the critical issue of dose, Plaintiffs' experts do not demonstrate that they thoroughly considered and ruled out alternative causes of the claimed health injuries. As described in section 3.4.4 the claimed symptoms are non-specific, frequently occur among flight

attendants in general, and have myriad potential causes. Even the specific diagnosis of occupational contact dermatitis, which is highlighted by Dr. Scheinman, has numerous potential causes, as noted in section 3.5.6. Without giving due consideration to each Plaintiff's history of each of these alternative causes, Plaintiffs' experts cannot reasonably conclude with confidence that chemicals in the Uniforms, as opposed to other common exposures, underlying medical conditions, or psychogenic factors, caused the claimed health conditions.

3.3.3 Plaintiffs' experts make causation determinations for all Plaintiffs despite having reviewed partial medical records (if any) and unvalidated health reports for a small minority of individual Plaintiffs, who are not established as being representative of Plaintiffs overall.

As outlined above in section 3.1.4, the National Research Council's Committee on Science, Technology, Law, Policy, and Global Affairs defines specific causation as addressing the question of "[D]id a particular stimulus cause a particular consequence in a specific instance"? (NRC, 2011). As part of a medical toxicologist's process of determining the cause of a plaintiff's injury, the National Research Council states (NRC, 2011):

> [I]t is widely recognized that a thorough medical history involves the questioning and examination of the patient as well as appropriate medical testing. The patient's written medical records also should be examined. The following information is relevant to a patient's medical history: past and present occupational and environmental history and exposure to toxic agents; lifestyle characteristics (e.g., use of nicotine and alcohol); family medical history (i.e., medical conditions and diseases of relatives); and personal medical history (i.e., present symptoms and results of medical tests as well as past injuries, medical conditions, diseases, surgical procedures, and medical test results).

In his report, Dr. Freeman claims to conduct a "Specific Causation Analysis" for 908 Plaintiffs who self-reported health symptoms after wearing the Uniforms. According to Dr. Freeman, a specific causation analysis involves a determination of whether "[t]hat exposure caused this outcome, illness, injury. So it's – it's specific to facts in the case that include facts of exposure and some information on what kind of injury or disease process would have followed it" (Deposition of Michael Freeman, pp. 53–54). The sole source of information for his self-described specific causation analysis, however, consists of unvalidated health information supplied by Plaintiffs in a questionnaire distributed by Lands' End (discussed further in section 3.4.1).

Despite acknowledging that specific causation pertains to determination of causes in individual persons (Deposition of Michael Freeman, pp. 52, 54–55), Dr. Freeman never reviewed, received, or asked to review any medical records pertaining to any Plaintiffs in this matter

(Deposition of Michael Freeman, pp. 58–59). Instead, he testified: "The present time I – my analysis is limited to as far as individuals just what I've gleaned from the questionnaires" (Deposition of Michael Freeman, p. 61). As noted by the National Research Council (NRC, 2011), "In assessing whether the data may reflect inaccurate information, one must assess whether the data were collected from objective and reliable source." Dr. Freeman, however, appears not to have questioned the objectivity and reliability of Plaintiffs' self-reported symptom questionnaire data, and did not seek confirmatory evidence from medical records. In the absence of medical records, Dr. Freeman has no clinical confirmation of Plaintiffs' self-reported health symptoms and no clinical information on Plaintiffs' medical history, including any underlying health conditions that could explain their claimed symptoms (discussed further in section 3.4.4). Thus, Dr. Freeman has no objective basis for identifying the specific health complaints of any individual Plaintiff, or for evaluating alternative causes of those health conditions.

Dr. Scheinman makes causation determinations for all Plaintiffs despite having partial medical information on only approximately 15 or 16 Plaintiffs (Deposition of Pamela Scheinman, pp. 86–87). Dr. Scheinman testified that she was unaware how Plaintiffs' medical records were selected for her review by Plaintiffs' counsel; therefore, she could not ascertain whether these individuals were representative of the entire population of claimants (Deposition of Pamela Scheinman, pp. 126–127). In addition, she was given skin patch test results from only seven Plaintiffs (four of whom were tested against the Uniforms), even though NIOSH reported that as of mid-May 2019, 33 Delta employees had undergone patch testing as part of their medical evaluations for potential Uniform-related health effects (NIOSH, 2019). Dr. Scheinman testified during her deposition that she did not provide any guidance on how to select a representative sample of Plaintiffs' medical records for her review; on the contrary, the medical records provided to her by Plaintiffs' counsel were "presented to [her as] a representative group," and she did not question the representativeness of this subset or request any additional medical information besides what she was given (Deposition of Pamela Scheinman, p. 127).

Dr. Apple testified in his deposition that he reviewed partial medical records for only 22 Plaintiffs, and he never requested medical information on the approximately 980 other Plaintiffs in this matter (Deposition of Fred Apple, pp. 98–99). When whether he received complete medical records for any Plaintiff, Dr Apple responded, "I would say, no" (Deposition of Fred Apple, p. 100). He confirmed that he played no role in choosing which documents he received from Plaintiffs' counsel (Deposition of Fred Apple, p. 97). Although Dr. Apple stated that it was his "understanding" that the 22 selected Plaintiffs were a "representative sample" of all Plaintiffs, he testified that his basis for this understanding was a summary document listing Plaintiffs' symptoms, yet he did not know who assembled that summary or whether it was based on Plaintiffs' self-reports or medical records (Deposition of Fred Apple, pp. 100–101).[1] Dr.

[1] The summary document appears to be the "Quantitative Summary of Medical Injuries Related to Delta Uniforms" (Apple01770).

Apple did not report that he made any systematic comparison between characteristics of the 22 selected Plaintiffs for whom he reviewed some medical records and characteristics of the Plaintiffs summarized in the document.

For a sample to be fairly representative of a larger population, the sample should be selected randomly according to a probability method (i.e., using a structured, reproducible selection process where each individual in the population has a known (usually equal) probability of being in the sample) (NRC, 2011). Sample representativeness can be evaluated by systematically comparing characteristics, such as demographics, exposure history, and health status, between the selected sample and the underlying population. No Plaintiffs' expert, however, has established that the small proportion of Plaintiffs whose partial medical records they reviewed (if any; Dr. Freeman did not review medical records for any Plaintiff) were randomly selected or that the distribution of their characteristics matches that of the overall population of all Plaintiffs.

3.3.4 Chemicals identified by Plaintiffs' experts as posing a health hazard are common exposures that follow dose-response patterns, many of which differ by exposure route.

Plaintiffs' experts Dr. Freeman, Dr. Scheinman, and Dr. Apple identify several chemicals as having been detected in the Uniforms, with some levels that they describe as exceeding OEKO-TEX® standards and, according to their interpretation, consequently posing a health risk to employees. Chemicals of concern identified by Plaintiffs' experts include aluminum, antimony, arsenic, barium, bromine, chromium, copper, fluorine, formaldehyde, lead, magnesium, mercury, nickel, silicon, and sodium. Dr. Freeman also states that phthalates were "found in the uniforms," but does not cite quantitative levels and provides no test results to support this assertion.[2] Dr. Scheinman notes that some Plaintiffs showed positive patch testing reactions to textile blue and orange dyes (specifically, disperse blue 106, disperse blue 124, and disperse orange 3), but she does not provide test results showing levels of these dyes, if any, in the Uniforms.[3]

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[2] Phthalates are a family of chemicals used as plasticizers or solvents in a wide variety of products, such as vinyl flooring and wall coverings, adhesives, detergents, lubricating oils, automotive plastics, plastic clothing, personal-care products (e.g., shampoos, nail polishes, perfumes, hair sprays, aftershaves, and soaps), food packaging, garden hoses, inflatable toys, blood-storage containers, medical tubing, pharmaceutical products, and children's toys (Centers for Disease Control and Prevention (CDC), 2017; Food and Drug Administration (FDA), 2020b). According to FDA (2020b), "[i]t's not clear what effect, if any, phthalates have on human health." According to CDC (2017), "[h]uman health effects from exposure to low levels of phthalates are unknown." As described in the Intertox report, Hohenstein Laboratories tested Uniforms for phthalates according to the OEKO-TEX® 100 Standard, and detections were not reported.

[3] Disperse dyes are a class of synthetic, water-insoluble dyes that are used to dye hydrophobic synthetic fibers such as polyester, acetate, polyamide, acrylic, and nylon (AFIRM Group, 2018). Certain disperse dyes,

According to ATSDR, USEPA, NIOSH, and other health and regulatory agencies, aluminum, antimony, arsenic, barium, bromine, chromium, copper, fluorine, formaldehyde, lead, magnesium, mercury, nickel, silicon, and sodium are commonly found in the environment, such as foods, drinking water, soil, ambient air, and/or consumer products (USEPA, 1988, 1998a, 1998b, 1998c, 2002b, 2002c, 2002d, 2002e, 2004, 2005, 2006, 2010, 2020a; ATSDR, 1999a, 1999b, 2003, 2004a, 2005, 2007a, 2007b, 2008, 2012, 2019a, 2019b, 2020; NRC, 2010a, 2010b; FDA, 2020c; NIOSH, 2020; National Institutes of Health, 2020). These background exposure levels are generally considered not to be harmful to human health. Some of these chemicals, such as chromium, copper, magnesium, and sodium, are even essential for human life, and formaldehyde is produced naturally in the human body by metabolic processes.

Of critical importance in this matter is that all of these chemicals exhibit dose-response effects, with toxicity varying by dose, route of exposure (e.g., with different effects for oral vs. dermal exposure), and chemical form or compound (e.g., with different effects for inorganic vs. organic arsenic compounds, hexavalent vs. trivalent chromium, and metallic vs. inorganic vs. organic mercury). Many of these agents have been observed to have certain adverse health effects only at high occupational levels of exposure in workers—levels that have not been demonstrated in this matter.[4] Moreover, regulatory values have been established for all of these chemicals, meaning that they are all considered by regulatory and health agencies to have levels below which adverse human health effects are not anticipated to occur, even in sensitive populations. Thus, the presence of any of these chemicals in the Uniforms does not, in and of itself, constitute a health hazard. On the contrary, evaluation of the dose (including magnitude, duration, frequency, and timing of exposure), exposure route, and chemical form(s) or compound(s) at issue is crucial to evaluating medical causation for the Plaintiffs in this matter.

3.3.5 Plaintiffs' experts inappropriately rely on garment test results for total metal levels and garments that were previously worn, and they do not acknowledge inherent limitations of the testing approach.

Plaintiffs' approach to testing for chemicals in the Uniforms appears to deviate from standard, generally accepted methods that measure releasable (extractable) chemicals rather than total chemical content. Garments can be tested for chemical content according to two general methods. First, one can measure the total amount of a chemical (e.g., a specific metal) in and on the garment. This testing is typically performed by first destructively pre-treating the garment to

including the ones specified by Dr. Scheinman (disperse blue 106, disperse blue 124, and disperse orange 3), are suspected of causing allergic reactions (AFIRM Group, 2018). These dyes, however, were not identified in the Intertox or other test reports pertaining to the Uniforms.

[4] Regulatory effects to control workplace exposures to hazard agents typically focus on inhalation exposures to airborne substances, as opposed to dermal exposures (NIOSH, 2013). Units of inhalation exposure (e.g., µg per cubic meter of air) are not directly comparable to units of dermal exposure (e.g., µg per gram of textile).

release the chemical contents of interest (e.g., metals) to make them available for testing (i.e., a sample preparation phase), followed by a testing phase.

The second type of testing focuses on measuring the amount of chemicals that can be leached or released from the garment materials, under laboratory conditions that simulate those that might occur from human use, for example, exposure to heat or human sweat. Logically, the total amount of a substance present in the garment is greater than (or at most equal to) the amount that can be released. Consequently, different standards exist for total and extractable chemicals.

According to a research report conducted for the U.S. Consumer Product Safety Commission (CPSC), the most common metals found in textile dyes are chromium, copper, nickel, and cobalt (Greenpeace, 2005; TERA, 2016). These metals, however, are expected to be bound in the dye matrix, with copper and nickel bound in phthalocyanine dyes, copper bound in reactive dyes, and chromium bound in metal-complex acid dyes (European Commission, 2003). Bound metals are therefore "minimally bioavailable once incorporated into the dye," and the dyeing process is designed by manufacturers to minimize metal loss (TERA, 2016). Phthalocyanine dyes are resistant to extraction by human sweat because they are not water-soluble, and they are resistant to extraction/volatilization by heat because they have a very low vapor pressure (PubChem, 2021a). Reactive dyes and acid dyes are chemically bonded to fiber materials, also making bound metals resistant to extraction or leaching (Textile Property, 2020a, 2020b). Bound metals are thus considered "of lesser concern for human and environmental exposures" (TERA, 2016). Given that releasable chemicals in garments are the exposure of relevance to human health, Plaintiffs' experts' focus on total chemical levels, rather than releasable, leachable, or extractable chemical levels, lacks scientific validity.

Another limitation of Plaintiffs' experts' reliance on Uniform test results arises from apparent testing of previously worn Uniforms that were supplied by Plaintiffs. Testing of worn garments is unreliable for identification of chemicals from textile dyes because any detected substances cannot reliably be attributed to the garments themselves, as opposed to foods, consumer products, environmental exposures encountered throughout daily life. Chromium, copper, nickel, and cobalt, for instance, are commonly found in personal care products (e.g., lotions, perfumes, and deodorants) and cosmetics, household items, food, water, ambient air, and cigarette smoke (ATSDR 2004a, 2004b. 2005, 2012; Hepp, 2014; FDA, 2020a). Therefore, chemicals measured in previously worn garments may be derived from any or all of these alternative sources, rather than textile dyes.

Plaintiffs' experts largely ignore inconsistent test results (e.g., detected chemical levels in some Uniform items but not others made with the same materials and dye colors) and gaps in testing (e.g., testing for certain groups of chemicals but not others in a given Uniform item). Plaintiffs' experts also ignore the negative test results of Bureau Veritas, which found no detectable extractable formaldehyde, chlorinated phenols, dimethyl fumarate, alkylphenols, alkylphenol

ethoxylates, potentially allergenic or carcinogenic dyes, volatile organic compound emissions, cadmium, cobalt, mercury, lead, antimony, or hexavalent chromium, and no exceedances of OEKO-TEX® Standard 100 limits for arsenic, chromium, copper, and nickel in Class II products (i.e., garments worn close to the skin), in 30 tested Uniform materials. Finally, Plaintiffs' experts ignore the test results presented in the November 11, 2019, report of Intertox, Inc., which reported no allergenic organic chemicals and only three detectable potential inorganic allergens (zinc, copper, and titanium) based on testing by Avomeen Laboratories; and nearly no exceedances of OEKO-TEX® Standard 100 Product Class II limits based on testing by Hohenstein Textile Testing Institute, except for three apron exemplars that exceeded the standard allowable limit for perfluorooctanoic acid (and one women's pants exemplar that was at the allowable limit when first tested and below the allowable limit when retested), and one vest lining exemplar that failed the test for colorfastness[5] to saliva and perspiration, but did not exceed any of the chemical test limits (Table B3 in Appendix B).

Plaintiffs' experts appear to interpret test results for crocking or colorfastness as if they were a proxy for surface wipe testing, which would show transfer of metal from the surface of a garment fabric to a test fabric surface, which can then be digested and assessed for metal content (e.g., USEPA SW-846[6]). Reliable conclusions about metal exposures cannot be drawn based on test results for crocking or colorfastness. Besides the fact that any detected substances are not necessarily attributable to the garment itself, as opposed to the environment or the test materials, another major problem is that there is no colorimetric correlation between any transferred color and metal content. Therefore, transfer of color cannot be assumed to equate to the transfer of metal or the quantitative concentration of metal on or in fabric.

Taken together, the tests of total instead of extractable chemicals, tests of worn uniforms (including, in some instances, old uniforms that are distinct from the Uniforms at issue), and inconsistent laboratory findings render Plaintiffs' garment test results inconclusive and largely uninformative for assessing Plaintiffs' exposures to Uniforms.

3.3.6 Plaintiffs' experts misinterpret textile garment standards, resulting in erroneous conclusions that levels of metals in the Uniforms exceeded applicable OEKO-TEX® standards.

As stated earlier, OEKO-TEX® specifies standards to test for toxic substances in textiles and ensure that their levels are "harmless for human health," taking into account "numerous regulated and non-regulated substances" (OEKO-TEX®, 2021). OEKO-TEX® Standard 100 specifies two types of tests for heavy metals, "extractable" and "total," with different values for

[5] "Fastness" or "colorfastness" refers to a textile's ability to retain color when subjected to various environmental conditions such as perspiration, cleaning, and other activities.

[6] https://www.epa.gov/hw-sw846

the same metal depending upon the type of test that is performed. OEKO-TEX® defines extractable metals as those measured using a testing approach that uses an artificial acidic sweat solution in accordance with International Organization for Standardization (ISO) 105-EO4 (OEKO-TEX®, 2021).

By contrast, OEKO-TEX® defines total metals as those measured in a garment after it has been digested with an acid solution prior to analytical testing. Thus, the key difference between total and extractable metals concerns how the sample is prepared prior to analysis. OEKO-TEX® indicates that the same type of analytical methodology, i.e., inductively coupled plasma (ICP) or atomic absorption spectroscopy (AAS), can be used to measure both total and extractable metal levels. However, greater amounts of metals can be released and detected by testing after a garment sample is subjected to acid digestion than when it is pre-treated with simulated sweat; consequently the OEKO-TEX® Standard 100 acceptable levels for total metals are higher than for those for the corresponding extractable level.

Dr. Freeman's misinterpretation of garment testing standards and results

Dr. Freeman's misapplication of the OEKO-TEX® standards is clearly illustrated in Table 2 of his report, where Dr. Freeman erroneously compares measured *total* metal levels with limit values for *extractable* metals according to OEKO-TEX® Standard 100. The tests that Dr. Freeman mistakenly identifies as showing metal levels above relevant OEKO-TEX® standards were analyzed by ALS Environmental using USEPA Method 6010D for metals other than mercury (UESPA, 2018) and USEPA 7471B for mercury (USEPA, 2007).[7]

USEPA 6010D is an analytical method for measuring metals in solid and aqueous samples that are digested prior to analysis using ICP-optical emission spectrometry (ICP-OES) (USEPA, 2018). Method 6010D does not assess the release of metals from textiles with the use of a simulated sweat solution, as specified in the OEKO-TEX® Standard 100 for *extractable* metals; instead, it involves sample digestion prior to analysis, in a manner applicable to the OEKO-TEX® Standard 100 for *total* metals.

USEPA 7471B is an analytical method approved for measuring total mercury (organic and inorganic) in soils, sediments, bottom deposits, and sludge-type materials (USEPA, 2007). Method 7471B requires that "All samples must be subjected to an appropriate dissolution step prior to analysis. If this dissolution procedure is not sufficient to dissolve a specific matrix type or sample, then this method is not applicable for that matrix" (USEPA, 2007). Thus, this method does not assess the release of mercury from a garment using an artificial sweat solution, as

[7] ALS Environmental reports # J1904629, J1905053, J2003716, J2003717, J2003720

required by the OEKO-TEX® Standard 100 for *extractable* metals; instead, it uses pre-analysis sample digestion, as specified by the OEKO-TEX® Standard 100 for *total* metals.

Thus, Dr. Freeman's use of OEKO-TEX® limit values for extractable metal levels in garments is inappropriate for comparison with levels measured in Uniform items that underwent testing using methods designed for quantifying total metal levels. His misapplication of the OEKO-TEX® limit values leads in turn to his erroneous conclusion that metals in the Uniforms exceeded relevant OEKO-TEX® standards. For example, the OEKO-TEX® Standard 100 for *total* mercury in Class II products is 0.5 parts per million (ppm), i.e., 25 times greater than the OEKO-TEX® standard for *extractable* mercury of 0.02 ppm, which is the limit value cited by Dr. Freeman. The concentrations of total mercury measured (if at all) in all Uniform items listed in Table 2 of Dr. Freeman's report are well below the applicable OEKO-TEX® Standard 100 limit value for total mercury in Class II products. Likewise, Dr. Freeman's conclusion that levels of antimony and chromium measured in the Uniforms exceed OEKO-TEX® standards is false, based on his inappropriate application of extractable metals standards to results for total metal content.[8] In fact, none of the metal levels measured (if at all) in Uniform items listed in Table 2 of Dr. Freeman's report exceed any applicable OEKO-TEX® Standard 100 limit value for metals in Class II products.

Dr. Scheinman's misinterpretation of garment testing standards and results

Similarly, Dr. Scheinman relies upon the OEKO-TEX® standards as benchmarks to evaluate whether levels of chemicals in garments were increased (Deposition of Pamela Scheinman, p. 163). Yet, Dr. Scheinman acknowledged in her deposition that she does not have "expertise on appropriate limitations" (i.e., exposure limits) for metal levels in garments (Deposition of Pamela Scheinman, pp. 163–164).

In her reports, Dr. Scheinman states that "high" mercury levels were detected by Enthalpy Analytical in a ladies' blazer (0.024 ppm) and a pair of ladies' pants (0.059 ppm).[9] According to the laboratory report, Enthalpy analyzed these garments using several analytical methods. USEPA Method 6020 was used to measure levels of metals other than mercury and hexavalent chromium, and USEPA Method 3050B was used to prepare the garment samples for analysis by USEPA Method 6020. Mercury was measured using USEPA Method 7471A, and hexavalent chromium was measured using USEPA Method 7196A These methods all involve sample digestion prior to analysis and are intended to measure total metal concentrations (USEPA, 1992, 1994a, 1994b, 1996). None of the methods employed by Enthalpy Analytical to test these

[8] OEKO-TEX® Standard 100 does not set standard limit values for total antimony or chromium. OEKO-TEX® sets *total* metal standards for only four metals (arsenic, cadmium, lead, and mercury), and *extractable* metal standards for these four metals as well as antimony, barium, chromium, chromium VI (hexavalent chromium), cobalt, copper, nickel, and selenium.

[9] Enthalpy Analytical report # 311031

garments were designed to measure extractable metal levels using an artificial sweat solution that would make the result applicable to the OEKO-TEX® Standard 100 extractable metal standards. In fact, no metals measured in any of the tested Uniform items (antimony, arsenic cadmium, chromium, hexavalent chromium, cobalt, copper, lead, mercury, and nickel) exceeded any applicable OEKO-TEX® Standard 100 metal standard.

Sweat provides a vehicle for transfer of chemicals from garments to the skin and subsequent absorption into the body. Thus, the potential for release of chemicals into sweat is an important factor in determining the potential of a garment to cause toxicity. The potential for metal release from garments into sweat can be assessed by a test that measures extractable metal levels using an artificial sweat solution. As summarized in the Intertox report, 18 Uniform items were tested for extractable metals by Bureau Veritas at the request of Lands' End. None of those tests revealed extractable metal levels exceeding any applicable OEKO-TEX® standard for extractable metals in Class II products. In addition, Intertox sent 93 Uniform items, randomly selected as exemplars from garments available from Lands' End in June 2019, to the Hohenstein Textile Testing Institute for extractable metals analysis. Again, none of those tests revealed extractable metal levels that exceeded any relevant OEKO-TEX® standard.

Despite testifying repeatedly that sweating can influence any dermal effect of chemicals in garments (Deposition of Pamela Scheinman, pp. 50, 97, 129, 163, 179, 254, 258, and 264), Dr. Scheinman appears to disregard the test results for extractable metal levels, and instead relies upon total metal results in reaching her causation determination, for example, for mercury and alopecia. A review of test results for mercury and other heavy metals reported by Enthalpy Analytical and ALS Environmental reveals that 72 Uniform items underwent such testing (Table B1 in Appendix B). Of the 46 garments tested for mercury, 10 had total mercury levels at or above 0.02 ppm, the limit value for extractable mercury that Dr. Scheinman and Dr. Freeman mistakenly took as the relevant OEKO-TEX® standard applicable to these tests. All total mercury levels were below the relevant OEKO-TEX® standard of 0.5 ppm for total mercury. All other metal levels were reported by Enthalpy Analytical and ALS Environmental were also below the relevant OEKO-TEX® Standard 100 limit values for Class II products.

Thus, Dr. Scheinman appears to have made multiple errors in her interpretation of metal levels in the Uniforms. First, she cherry picks from the minority of Uniform items at the higher end of the distribution of mercury test results, and generalizes these findings to explain the occurrence of alopecia, a common complaint among all Plaintiffs (discussed further below). Second, she disregards the Bureau Veritas and Hohenstein Textile Testing Institute test results for extractable metals that show no significant metal release from the Uniforms. Third, she compares total metal levels measured by ALS Environmental and Enthalpy Analytical with OEKO-TEX® Standard 100 limit values for extractable levels, even though total metals measured in acid-digested garments cannot be established to be related to releasable metal levels.

Dr. Apple's misinterpretation of garment testing standards and results

In his report, Dr. Apple states that his causation opinions are based on the results of various laboratory tests performed on the Uniforms, including reports from Vartest, ALS Environmental, Enthalpy Analytical, TexTest, and Hohenstein Textile Testing Institute. In particular, he refers to "extremely high levels" of chromium, and fluorine, "high levels" of bromine, and "elevated levels" of antimony, barium, chromium, and nickel in certain Uniform items tested by ALS Environmental; "elevated levels" of antimony, chromium, and mercury in certain Uniform items tested by Enthalpy Analytical; "elevated levels" of formaldehyde in certain Uniform items tested by TexTest; and "elevated" levels of free and partially releasable formaldehyde in certain Uniform items tested by Hohenstein Textile Testing Institute. Dr. Apple testified during his deposition that where he referred to "extremely high levels," it was not with reference to any industry standards for textiles (Deposition of Fred Apple, p. 151). Instead, he stated that "they either reported it that way or it was multiple folds higher than what their upper value would have been" (Deposition of Fred Apple, p. 150). Dr. Apple did not identify the basis for characterization of other test results as "high" or "elevated." He also did not explain the difference between total and extractable chemical levels in textile testing (Deposition of Fred Apple, p. 113), although he confirmed that, in theory, a test result for total material in a garment might differ from a test result from extractable material (Deposition of Fred Apple, p. 113).

Review of the ALS Environmental reports relied upon by Dr. Apple,[10] however, reveals that none of those reports referred to "extremely high" or even "high" levels of any chemical in the tested Uniforms, and the word "elevated" was used only in reference to increased method reporting limits and/or method detection limits due to methodological issues such as sample matrix interference – that is, reduced sensitivity of the testing method, *not* test results showing elevated levels of any chemical. In fact, the ALS Environmental reports do not identify any upper limit value for total chromium in garments, nor do they contain reference ranges or expected ranges to make a determination of whether measured concentrations of any chemical were elevated or different from expected levels. Finally, Dr. Apple fails to discuss the ALS Environmental test results for Delta uniforms designed by Richard Tyler and worn by Plaintiffs before the introduction of the new Uniforms. In these garments, which are not considered by Plaintiffs to be problematic, the total chromium levels were higher than those in the Uniforms, ranging from 616 to 1,500 ppm (Table B2 in Appendix B).[11]

[10] ALS Environmental reports # J1904629, J1905053, J905056, J1906234, and J1906237 pertain to the Uniforms designed by Zac Posen. ALS Environmental reports # J2003716, J2003717, and J2003720 pertain to the older Delta uniforms designed by Richard Tyler.

[11] ALS Environmental does not specify whether the Richard Tyler uniforms were previously worn. If so, test results may have been affected by chemicals from other sources during use.

3.4 Response to Dr. Freeman's opinions

In addition to the problems shared with other Plaintiffs' experts, discussed above, Dr. Freeman expresses causation opinions that are undermined by their basis on unreliable questionnaire data from a selective subset of Delta employees; his superficial and incomplete evaluation of a subset of Hill causality guidelines based on scientifically inappropriate sources; his inapposite use of the Naranjo scale for evaluation of adverse clinical drug reactions; and his failure to rule out alternative causes of the symptoms reported in the Plaintiffs' questionnaire. I address these issues in the following sections.

3.4.1 Dr. Freeman's use of Plaintiffs' questionnaire data as a basis to evaluate general causation is scientifically invalid. These data cannot be used to estimate statistical associations, much less establish causal links, between exposure to the Uniforms and the onset of adverse symptoms.

In his report, Dr. Freeman summarizes questionnaire data from 982 (89%) of 1,098 Plaintiffs who completed a questionnaire issued by Lands' End, including 915 Plaintiffs (83%) who reported having worn Uniform items. In particular, Dr. Freeman focuses on question 11 from the survey (presented in Appendix I of Dr. Freeman's report), as follows:

> 11. In the following section, list any and all health symptoms or conditions you presently have or have had in the past that you claim are a result of the Uniforms. If possible, state when the symptoms started, as well as when they stopped. If symptoms still persist, write "still present." Also indicate whether you believe you are seeking compensation for the condition. Health symptoms (describe):

Logically, any symptoms that first occurred prior to wearing the Uniform cannot be causally attributed to chemicals in the garments. Therefore, such symptoms should have been excluded from or at least separately considered in Dr. Freeman's analysis, yet he does not state whether he did so.

More importantly, the questionnaire data are not a valid basis for identifying a statistical association, much less a causal relationship, between exposure to chemicals in the garments and risk of the symptoms reported by the Plaintiffs. First, the questionnaire was completed only by Plaintiffs in this matter after litigation began, that is, by Delta employees who claim health injuries from the Uniforms. No information is available from Delta employees who wore the Uniforms but did not report any symptoms; employees who did not wear the Uniforms but reported symptoms; or employees who did not wear the Uniforms and did not report any symptoms. A relative risk compares the probability of a health outcome in an exposed group to that in an unexposed group; that is, it is a measure of whether a given health outcome occurs more or less often among exposed people than unexposed people. Without such a comparison,

one cannot determine whether the reported frequency of symptoms among Delta employees who wore the Uniforms is higher than, lower than, or equal to that among Delta employees who did not wear the Uniforms.

To calculate a relative risk for the association between wearing the Uniforms and subsequent health symptoms, information from all of these groups is required (Figure 1).

Figure 1. 2 × 2 table of exposure status and health outcome status for estimating relative risk

		Symptoms		
		Yes	**No**	**Total**
New Uniforms	**Yes**	*A*	*B*	*A+B*
	No	*C*	*D*	*C+D*

For example, a risk ratio (a type of relative risk) would be calculated as the proportion of employees who wore the Uniforms and reported symptoms [*A/(A+B)*] divided by the proportion of employees who did not wear the Uniforms and reported symptoms [*C/(C+D)*]. The questionnaire, however, provides data almost exclusively on Plaintiffs who fall into group *A* for at least one symptom. According to Dr. Freeman's Figure 3, only 7 (0.8%) of 915 Plaintiffs reported no symptoms; the mean number of reported symptoms was 4.26 and the median was 4. Thus, the questionnaire selectively omits individuals from groups *B*, *C*, and *D*, precluding calculation of a valid relative risk. Instead, by consisting almost exclusively of individuals in group *A*, the questionnaire data are essentially equivalent to a case series, which is an invalid basis for determining causation, as described by Hennekens and Buring (1987) in a classic textbook on epidemiology (emphasis added):

> While case reports and case series are very useful for hypothesis formulation, *they cannot be used to test for the presence of a valid statistical association*. One fundamental limitation of the case report is that it is based on the experience of only one person. The presence of any risk factor, however suggestive, may simply be coincidental. Although case series are frequently sufficiently large to permit quantification of frequency of an exposure, *the interpretability of such information is severely limited by the lack of an appropriate control group*. This lack can either obscure a relationship or suggest an association where none actually exists.

A second problem with Dr. Freeman's reliance on data from the questionnaire is that symptoms were self-reported retrospectively by Plaintiffs who were aware of whether or not they wore the Uniforms. In observational epidemiological studies, to reduce bias, study investigators who assess and classify health outcomes are preferably blinded to participants' exposure status (Viswanathan et al., 2013; Higgins et al., 2020). For the Plaintiffs' questionnaire, however, self-reported symptoms were not independently validated by assessors blinded to participants'

exposure status (and, in any case, few Plaintiffs report not having worn the Uniforms). When participants provide self-reported health outcome data and are aware of their exposure status—and, in the context of litigation, when some participants may be motivated by personal gain—results are highly susceptible to detection bias, that is, a tendency to overreport adverse health outcomes in the exposed population, resulting in falsely inflated exposure-outcome associations.

A third problem relates to the structure of the questionnaire, namely, that Plaintiffs were asked to list "any and all health symptoms or conditions," whether present or past, that they claimed were a result of the Uniforms. The questionnaire, however, did not include any quality-control questions designed to ensure that participants were carefully reading and responding to the questions, and distinguishing among symptoms that might or might not be attributable to exposure to chemicals from the uniforms. A questionnaire designed to test the validity of reported health data, for instance, might have included a multiple-choice question listing specific symptoms known or suspected to be related to exposures to such chemicals, but also including symptoms known not to be associated with chemical exposures (e.g., fever, low back pain), as a quality-control measure. Such quality-control questions can enable exclusion of poor-quality data from analysis (Statistics Sweden, 2006), whereas the absence of such measures preclude the identification of unreliable data.

Finally, Dr. Freeman's interpretation of the questionnaire results is scientifically unsound. Dr. Freeman asserts that the data "very clearly demonstrated the appropriate temporal sequence of new symptoms resulting from the new uniform use." On the contrary, because claimed symptoms both before and after the introduction of the Uniforms were self-reported retrospectively at the same point in time after the commencement of litigation in this matter, the data cannot be relied upon as properly demonstrating the temporal sequence of the claimed exposure preceding the claimed health outcomes. The same limitation applies to the results that Dr. Freeman describes as supporting the "dechallenge criterion": claimed symptoms both during and after use of the Uniforms were self-reported retrospectively in the context of litigation. Only prospectively collected data, with symptoms documented first before the Uniforms were issued, again during the period when they were worn, and finally after they were no longer worn, would establish the temporal sequence of events in this context, thereby potentially providing reliable "challenge-dechallenge" test results.

Even if a proper temporal sequence were demonstrated between wearing the Uniforms and the onset and resolution of acute health symptoms, that information on its own would not establish causality. Thorough consideration of the relevant exposure characteristics, the particular symptoms at issue, and potential alternative causes (some of which can also vary with time, such as underlying health status, diet, and psychological stress) would still be necessary.

In light of the non-representative survey population, which was highly skewed toward exposed and symptomatic Plaintiffs (as opposed to exposed and non-symptomatic, non-exposed and

symptomatic, or non-exposed and non-symptomatic individuals, who were preferentially excluded); the unblinded, unvalidated, retrospective nature of the self-reported data on exposures and symptoms; the lack of built-in quality-control questions in the survey; and the overarching context of litigation, the questionnaire results are highly likely to be biased and, therefore, unreliable as a basis for causal inference.

3.4.2 Dr. Freeman's use of selected Hill causality guidelines and his reliance on selected case reports and exposure assessment studies for his general causation analysis is superficial, incomplete, and scientifically unreliable.

Dr. Freeman acknowledges in his report that the guidelines first promulgated by Sir Austin Bradford Hill (Hill, 1965) are generally used to evaluate general causation. As stated by Hill, these nine guidelines are intended for systematic assessment of causation in the following scenario: "Our observations reveal an association between two variables, perfectly clear-cut and beyond what we would care to attribute to the play of chance. What aspects of that association should we especially consider before deciding that the most likely interpretation of it is causation?" As described by Hill (1965), and summarized by Dr. Freeman in Appendix II of his report, the guidelines include the following nine considerations:

- **Strength**, i.e., the magnitude of the observed association between the exposure and the health outcome of interest. All else being equal, strong associations are less likely than weak associations to be due to confounding or bias.
- **Consistency**, i.e., repeated observation of an association between the exposure and the health outcome of interest by different investigators across different study settings. Repetition helps to reduce the probability of chance as an explanation for an observed association.
- **Specificity**, i.e., limitation of an observed association to a single exposure and a single health effect. Absence of specificity does not necessarily reduce the likelihood of causality.
- **Temporality**, i.e., the sequence by which a cause must precede an effect in time.
- **Biological gradient**, i.e., an exposure-response trend by which occurrence of the health outcome increases in accordance with greater exposure.
- **Plausibility**, i.e., credibility of a causal relation based on current knowledge in toxicology, biology, and other fields. Whether a causal effect is plausible depends on currently available scientific evidence, which is subject to change.
- **Coherence**, i.e., accordance of a causal relationship with the known natural history and biology of the health outcome of interest. Whether these lines of evidence are deemed to be coherent depends on currently available scientific evidence, which is subject to change.

- **Experiment**, i.e., evidence from studies with controlled or quasi-controlled exposures, such as interventions or preventive actions.
- **Analogy**, i.e., comparability of the available body of scientific evidence to that of similar exposure-outcome associations. Various analogies can be postulated to support or oppose a causal relationship, and do not necessarily enhance or reduce the likelihood of causality.

In his report, however, Dr. Freeman claims that "the Hill criteria have been distilled into a 3-step approach" that takes only two of the Hill guidelines into consideration (plausibility and temporality), as well as a third factor that Dr. Freeman refers to as "alternative cause." Alternative causes are discussed in section 3.4.4 below.

As discussed below, Dr. Freeman's dismissal of the other Hill guidelines is not scientifically justified. Even based on his considerations of temporality and plausibility, however, Dr. Freeman's analysis is flawed. To support the **temporality** of a causal effect of chemicals in the uniforms on the Plaintiffs' claimed injuries, Dr. Freeman cites findings from the Plaintiffs' symptom questionnaire. As explained in the prior section, all of the questionnaire data were self-reported retrospectively at a single point in time, after the claimed exposures and onset of symptoms. Consequently, these data are not a valid basis for establishing the temporal sequence of exposure to the Uniforms and the onset of symptoms. To properly demonstrate temporality, a survey should be prospective, first evaluating exposure and then evaluating health outcomes at a later time. The retrospective nature of the Plaintiffs' symptoms questionnaire also precludes fulfillment of what Dr. Freeman refers to as the "dechallenge" and "rechallenge" criteria; to establish temporality, repeated assessment over at least six time points would be required to demonstrate the appropriate sequence of 1) exposure initiation, 2) subsequent onset of symptoms, 3) exposure cessation, 4) subsequent improvement or resolution of symptoms, 5) exposure re-initiation, and 6) subsequent return of symptoms.

To support the **plausibility** of a causal effect of chemicals in the uniforms on the Plaintiffs' claimed injuries, Dr. Freeman cites only one epidemiological study comparing the risk of specific health symptoms between individuals with and without potential exposure to certain garments or chemicals from garments (McNeely et al., 2018). This study's value, however, is severely limited by its high potential for selection bias. The analysis was based on 684 Alaska Airlines flight attendants who completed a health survey in 2007, whereas only 117 (17%) of these flight attendants participated in 2013 and 249 (36%) participated in 2015; only 65 subjects (10%) completed all three surveys. Symptoms were evaluated exclusively by self-report, with no independent validation by assessors blinded to exposure status. Potential exposure to new uniforms was classified based only on the year of the survey; no data were available on actual wearing of uniform items or exposure to specific chemicals from uniforms. The low participation rates in the 2013 and 2015 follow-up surveys, combined with participants' awareness of when the new uniforms were introduced, followed by approximately 800 formal

health complaints and a class-action lawsuit filed in 2012 (McNeely et al., 2018) create high potential for bias in the results due to selective participation of subjects with self-reported health complaints, and non-response of subjects who lacked symptoms. Thus, the results of this study cannot reasonably be interpreted as demonstrating an association between exposure to chemicals from the new uniforms and an increased risk of health symptoms, as opposed to a higher frequency of self-reported symptoms in a subgroup of flight attendants after they became aware of widespread health complaints and litigation in relation to those uniforms.

All of the other sources cited by Dr. Freeman to support plausibility are anecdotal stories, case reports, exposure studies without health data, and inconclusive review articles, none of which constitute a valid basis for a causal determination. As noted earlier, case reports and case series are not a valid basis for inferring causality, due to the lack of a suitable comparison group (Hennekens and Buring, 1987). Exposure assessments and health risk assessments also cannot test associations or causal hypotheses between exposures and health conditions because they lack observed data on health outcomes. Dr. Freeman's sources are as follows:

- Websites describing anecdotal reports of health complaints among Transportation Security Administration airport workers who "blame[d] formaldehyde" in their new uniforms[12];
- Case reports of hair loss among patients who ingested copper (from tap water), arsenic, mercury, or cadmium (Pierard, 1979);
- A case report of a patient with metal hypersensitivity following total knee arthroplasty with a prosthetic implant made of cobalt-chromium alloy (Post et al., 2013);
- A review article on formaldehyde and formaldehyde-releasers, in which the authors note the following:

> What concentration of formaldehyde is safe for sensitive patients remains, even though several investigations have investigated this issue, largely unknown. There is a lack of eliciting threshold data based on systematic investigations and an obvious need for experimental studies illustrating the relevance of formaldehyde exposure in a dose-response manner on healthy and diseased skin in formaldehyde-sensitive individuals (de Groot et al., 2009);

- Case reports of patients with contact dermatitis attributed to allergies to textile dyes or resins (Lazarov, 2004);

[12] https://oecotextiles.blog/2011/01/04/formaldehyde-in-your-fabrics/; https://www.washingtonpost.com/wp-dyn/content/article/2009/01/05/AR2009010502146.html; http://ashsd.afacwa.org/?zone=%2Funionactive%2Fview_article.cfm&HomeID=160011

- An exposure assessment study of levels of polybrominated diphenyl ethers in firefighter personal protective clothing, without any reports of related health complaints (Alexander and Baxter, 2016);
- A review article on the presence of various chemicals in clothing, without connection to actual health complaints, and a conclusion that risk assessments "show a non-negligible presence of various chemicals in some textiles, which *might* lead to *potential* systemic risks" (Rovira and Domingo, 2019; emphasis added);
- An exposure assessment and risk assessment study of levels of formaldehyde in European textiles, without connection to actual health complaints (Piccinini et al., 2007);
- Case reports of patients with formaldehyde textile resin allergy, based on patch testing (Fowler et al., 1992) – a method that de Groot et al. (2009), also cited by Dr. Freeman, describe as "problematic": "Former test concentrations of 3–5% resulted in many false-positive reactions. Currently, 1% aqua is the standard for patch testing. However, there are indications that this concentration is too low, resulting in (many) false-negative reactions";
- Case reports of patients with textile industry workers diagnosed with work-related allergic contact dermatitis, irritant contact dermatitis, or non-work-related allergens, irritants, atopy, or other dermatoses, most commonly among those with occupational exposure to raw textile products (Soni and Sherertz, 1996);
- Websites describing anecdotal reports of health complaints among Alaska Airlines flight attendants who attributed symptoms to their uniforms, and related litigation[13]; and
- Websites describing anecdotal reports of health complaints among American Airlines flight attendants who attributed symptoms to their uniforms[14].

Further, Dr. Freeman essentially ignores the other seven Hill guidelines of strength (other than claiming that the association that he detected using the Plaintiffs' questionnaire is "strong"), consistency, specificity, biological gradient, plausibility, coherence, experiment, and analogy. His failure to consider consistency and biological gradient is especially glaring. As stated in the National Research Council's Reference Manual of Scientific Evidence (NRC, 2011), which describes all nine Hill guidelines in its section on using epidemiology to evaluate general causation, a **biological gradient** usually exists between a causal exposure and a disease, such that a dose-response relationship provides "strong," albeit not essential, evidence of a causal relationship: "A dose-response relationship means that the greater the exposure, the greater the risk of disease. Generally, higher exposures should increase the incidence (or severity) of disease" (NRC, 2011). Dr. Freeman, however, provides no evidence to demonstrate a biological gradient between a higher frequency or severity of the claimed health symptoms and, for

[13] http://ashsd.afacwa.org/?zone=%2Funionactive%2Fview_article.cfm&HomeID=160011; https://www.prnewswire.com/news-releases/court-rules-in-favor-of-twin-hill-300337694.html

[14] https://www.afacwa.org/uniforms; https://www.dallasnews.com/business/local-companies/2017/01/24/american-airlines-flight-attendants-file-2600-complaints-but-uniform-issues-continue/; https://cdn.afacwa.org/docs/safety/chemical-testing-uniforms.pdf

instance, longer duration of wearing the Uniforms, wearing a greater number of Uniform items, higher levels of urinary, blood, hair, or toenail biomarkers for exposure to the chemicals at issue, or other proxies for exposure to the Uniforms or the claimed chemicals.

The National Research Council also highlights the importance of replicating research findings to establish the **consistency** of an association across independent study populations and research groups (NRC, 2011):

> Rarely, if ever, does a single study persuasively demonstrate a cause–effect relationship. It is important that a study be replicated in different populations and by different investigators before a causal relationship is accepted by epidemiologists and other scientists. The need to replicate research findings permeates most fields of science. In epidemiology, research findings often are replicated in different populations. Consistency in these findings is an important factor in making a judgment about causation.

By citing only one published epidemiological study showing a statistical association between year (i.e., after vs. before new uniforms were issued and a related class-action lawsuit was filed) and increased self-reported symptoms in a selected minority of flight attendants—and without referring to any studies examining health symptoms associated with dermal or respiratory exposure to specific chemical agents from garments at the levels at issue in this matter—Dr. Freeman provides no scientific evidence with which to evaluate the consistency of those potential association across independent study populations.

To evaluate the consistency of findings across studies in an unbiased, comprehensive, transparent, and reproducible manner, a systematic literature review should be conducted to identify and integrate all of the relevant scientific studies of a given research question. Components of a systematic literature review include specification of the research question at issue, use of a broad and clearly documented search strategy, uniform application of literature selection criteria, and rigorous critical assessment of the methodological quality and results of relevant studies based on standard, well-accepted considerations (e.g., Institute of Medicine, 2011; Agency for Healthcare Research and Quality, 2014; National Toxicology Program, 2015; U.S. Preventive Services Task Force, 2018). Yet, Dr. Freeman does not appear to have followed any of these steps; he does not document how he searched for, selected, or evaluated the studies that he chose to cite in support of his opinion. Therefore, even if the studies cited by Dr. Freeman demonstrated a consistent statistical association between exposure to certain garments or chemicals and the onset of various health symptoms—which they do not—his unsystematic approach to selecting those studies would reduce confidence in any conclusions based on a potentially non-representative segment of the scientific literature.

3.4.3 Dr. Freeman uses the Naranjo scale outside of its intended context of assessing adverse drug reactions in clinical settings. His use of this scale to evaluate general causation in this matter is scientifically inappropriate.

The Naranjo scale is described by its authors as a process for "estimation of the probability that a drug caused an adverse clinical event" (Naranjo et al., 1981). Dr. Freeman refers to the Naranjo scale as "a widely used algorithm designed to determine the likelihood of whether an adverse drug reaction is, in fact, due to the drug rather than other factors." However, he omits mentioning that Dr. Naranjo and co-authors developed the scale specifically for assessing adverse drug reactions in clinical contexts, where 1) there is a "[l]ack of a method for establishing causality"; 2) assessment of causation is "usually based on clinical judgment"; and 3) "often the adverse clinical event cannot be distinguished from manifestations of the disease" that the drug was intended to treat (Naranjo et al., 1981). More specifically, the U.S. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) states that the Naranjo scale was "designed for use in controlled trials and registration studies of new medications, rather than in routine clinical practice" (LiverTox, 2019). NIDDK also highlights that the Naranjo scale 4) "relies upon testing for drug levels" in "blood or other fluids," and 5) takes into consideration whether "the reaction reappears with administration of placebo" (Naranjo et al., 1981; LiverTox, 2019).

None of these conditions apply to the present matter. On the contrary, 1) there is a well-established and widely used method for assessing causality, namely, the Hill guidelines (Hill, 1965), which are accepted by the National Research Council and Federal Judicial Center as a standard approach to evaluating general causation (NRC, 2011). 2) Assessment of causation using the Hill framework is based not on clinical judgment, but on rigorous evaluation of the relevant epidemiological and related scientific literature, with "an understanding of the strengths and weaknesses of [each] study's design and implementation, as well as a judgment about how the study findings fit with other scientific knowledge" (NRC, 2011). 3) The Plaintiffs' health complaints are not potential symptoms of an underlying disease that prompted treatment with the exposure at issue, and the claimed symptoms arose outside the context of a clinical trial or registration study. 4) No testing was conducted to measure exposure to the claimed chemicals in blood, urine, or other biological specimens collected from Plaintiffs, and 5) placebo-controlled testing (e.g., with visually identical garments manufactured without the chemicals at issue) was not performed.

Besides inappropriately using the Naranjo scale outside of the clinical context of drug safety testing, Dr. Freeman misapplies the scale by purportedly using it to evaluate general causation, as opposed to specific causation. In the original publication by Naranjo et al. (1981), the authors applied their "adverse drug reaction probability scale" to 63 randomly selected adverse drug reactions published as *case reports* in major medical journals. That is, the Naranjo scale was developed for rating the probability of specific causation in individual persons, not general

causation among humans overall. The applicability of the Naranjo scale to specific rather than general causation is evident from questions that comprise the scale itself (e.g., "Did the patient have a similar reaction to the same or similar drugs in *any* previous exposure?"); the definitions of the probability classification levels (e.g., "A 'probable' reaction (1) followed a reasonable temporal sequence after a drug, (2) followed a recognized response to the suspected drug, (3) was confirmed by withdrawal but not by exposure to the drug, and (4) could not be reasonably explained by the known characteristics of the patient's clinical state"); the results of the rating study (e.g., "A 3-point between-raters disagreement occurred in only one very complicated case"); and the authors' discussion of uses of the scale (e.g., "When a patient receives several drugs at the same time the [adverse drug reaction] scale must be applied to each of the possible causes") (Naranjo et al., 1981; emphasis added). Again, Dr. Freeman eschews the standard scientific method of using the Hill guidelines to evaluate general causation, and instead attempts to use an approach that was not designed and is not accepted for this purpose.

3.4.4 The claimed symptoms, which are common in the general population and among flight attendants in particular, have numerous potential alternative causes that Dr. Freeman does not consider and exclude as plausible explanations.

According to the Complaint, as summarized by Dr. Freeman, the following signs and symptoms were reported by more than 20% of the Plaintiffs:

- Fatigue
- Skin irritation
- Rash
- Itchiness
- Hives
- Headaches
- Anxiety
- Memory issues
- Coughing
- Breathing difficulties
- Tightness of chest
- Hair loss
- Vocal cord issues/dysfunction

Dr. Freeman also summarizes questionnaire results indicating that the following symptom types and specific symptoms were reported by Plaintiffs after introduction of the Uniforms:

- Respiratory (symptom type)
- Dermatological (symptom type)
- Musculoskeletal (symptom type)
- Systemic (symptom type)
- Cardiovascular (symptom type)
- Genitourinary (symptom type)
- Neurological (symptom type)
- Reproductive (symptom type)
- Visual (symptom type)
- Gastrointestinal (symptom type)
- Endocrine (symptom type)
- Rash (symptom)
- Hair loss (symptom)

- Difficulty breathing or shortness of breath (symptom)
- Fatigue (symptom)
- Itching (symptom)
- Headache (symptom)
- Cough (symptom)
- Runny nose (symptom)
- Burning/itching/red eyes (symptom)
- Brain fog (symptom)

At a minimum, Dr. Freeman also should have summarized the responses to questions 13, 14, and 15 from the Plaintiffs' survey, given that these questions assessed potential alternative causes for the claimed symptoms, as follows:

> 13. Please list all known allergies, including but not limited to allergies to chemicals, prescription drugs, food, animals, pollen, and dust.
>
> 14. Please list any and all respiratory, cardiovascular, and/or dermatological illnesses you have ever had or been diagnosed with which you do not claim are related to the Uniform.
>
> 15. Please list any and all medications that you currently take or took during the time period in which you wore the Uniform.

Dr. Freeman fails to acknowledge potential causes of the claimed symptoms in general, and he provides no indication of having systematically considered and excluded such alternative causes for each Plaintiff. Instead, in a single sentence, he summarily dismisses the myriad known causes of these symptoms: "There are no apparent alternative explanations for the symptoms and injuries attributed by Delta personnel to the wearing of the new Lands' End uniforms."

On the contrary, numerous plausible alternative explanations exist for each of the claimed symptoms. For example, **rash**, the most frequently reported symptom according to the Plaintiffs' questionnaire, is commonly caused by various infections, heat, allergens, immune system disorders, medications, foods, emotional stress, and sunlight exposure (Mayo Clinic, 2019).

Hair loss, the second most frequently reported symptom, can be caused by aging, genetic susceptibility, hormonal changes (e.g., due to pregnancy, childbirth, menopause, or thyroid problems), immune system conditions, diabetes, scalp infections, certain medications and supplements, radiation therapy, sunlight, physical or emotional stress, substantial weight loss, excessive hairstyling, tight hairstyles, harsh hair treatments, hair-pulling disorders, poor nutrition, and cigarette smoking (Mayo Clinic, 2020a).

Difficulty breathing or shortness of breath, the third most frequently reported symptom, can be caused by deconditioning (being out of shape), obesity, anemia, anxiety disorders, asthma, anaphylaxis, carbon monoxide poisoning, cardiac tamponade, chronic obstructive pulmonary disease, myocardial infarction, heart arrhythmia, heart failure, other heart problems, pneumonia, other respiratory tract infections, collapsed lung, pulmonary embolism, upper airway obstruction, interstitial lung disease, pleural effusion, injured ribs, and various other conditions (Mayo Clinic, 2020b).

Fatigue, the fourth most frequently reported symptom, can be caused by excess physical activity, lack of physical activity, jet lag disorder, insufficient sleep, unhealthy eating habits, stress, sleep apnea, alcohol or drug use, certain medications and other treatments, anxiety disorders, chronic fatigue syndrome, chronic infection or inflammation, depression, diabetes, obesity, emphysema, fibromyalgia, grief, heart disease, hyperthyroidism, hypothyroidism, inflammatory bowel disease, persistent pain, and numerous other acute and chronic health problems (Mayo Clinic, 2020c).

Itching, the fifth most frequently reported symptom, can be caused by a variety of skin conditions (e.g., dry skin, eczema, psoriasis, scabies, parasites, burns, scars, insect bites, hives), psychiatric conditions (e.g., anxiety, depression, obsessive-compulsive disorder), internal disease (e.g., liver disease, kidney disease, anemia, diabetes, thyroid problems, multiple myeloma, lymphoma), nerve disorders (e.g., multiple sclerosis, pinched nerves, shingles), and a wide variety of irritants and allergens (e.g., wool, chemicals, soaps, lotions, other cosmetics, poison ivy or poison oak, certain medications) (Mayo Clinic, 2021a).

Similarly, numerous underlying causes have been identified for headache, cough, runny nose, burning/itching/red eyes, and “brain fog” or mild cognitive impairment (Mayo Clinic, 2021b).

Besides these common somatic causes of the claimed symptoms, psychogenic causes should also be considered as possible explanations for apparent clusters of non-specific health complaints in the workplace. Several studies have documented occurrences of unexplained sudden onset of non-specific symptoms among groups of co-workers at an airport, office buildings, and other occupational settings, with symptoms including headache, dizziness, faintness, throat irritation, nausea, numbness/weakness, chest tightness, vision problems, shortness of breath, vomiting, nausea, dry mouth, abdominal pain, eye irritation, and sleepiness (Stahl and Lebedun, 1975; Cohen et al., 1978; Colligan et al., 1979; Alexander and Fedoruk, 1986; Hall and Johnson, 1989; Hocking, 1990; Struewing and Gray, 1990; House and Holness, 1997; Bartholomew, 2005; Page et al., 2010). No explanatory chemical or other toxic exposures were identified in these settings, even with extensive environmental and industrial hygiene investigation, resulting in the conclusion that these were episodes of “mass psychogenic

illness." These examples illustrate that hundreds of co-workers can develop real and debilitating health symptoms without exposure to an identifiable toxic agent.

Of note, in the 2007 baseline study of the entire population of 3,985 flight attendants surveyed by McNeely et al. (2018), described above—but without the problem of selection bias created by comparing a small minority of repeated participants with the full group of original participants, and predating the introduction of new uniforms that engendered health complaints among Alaska Airlines flight attendants—at least 15% of flight attendants reported each of the following health conditions needing medical attention over the past 12 months (shown with 95% confidence intervals) (McNeely et al., 2014):

- Reactive airways/sinusitis/allergies: 54.7% (53.1–56.2%)
- Shortness of breath/reduced lung capacity: 15.5% (14.4–16.7%)
- Other respiratory symptoms: 14.6% (13.4–16.7%)
- Severe headache: 23.4% (22.1–24.7%)
- Numbness/tingling of extremities: 17.0% (15.8–18.2%)
- Dizziness/lightheadedness: 19.4% (18.1–20.6%)
- Memory loss/lack of concentration: 14.7% (13.6–15.8%)
- Fatigue: 36.8% (35.3–38.3%)
- Muscle weakness: 16.3% (15.1–17.5%)
- Joint aches/pains: 33.3% (31.8–38.8%)
- Rashes/hives: 15.5% (14.3–16.6%)

In addition, 29.0% (27.6–30.5%) of flight attendants reported frequent sinus congestion (lasting 5–7 days over the past week), 27.3% (25.9–28.7%) reported frequent fatigue, 20.0% (18.7–21.3%) reported frequent anxiety, and 23.3% (21.9–24.7%) reported frequent generalized muscle aches; and 19.4% (18.2–20.6%) reported ever having received a health care provider diagnosis of migraines, 17.0% (15.9–18.2%) were diagnosed with hearing loss, 33.7% (32.2–35.2%) were diagnosed with sleep disturbances, and 39.0% (37.5–40.6%) were diagnosed with allergies (McNeely et al., 2014). These results clearly indicate that regardless of uniform, due to various underlying causes, the complaints claimed by the Plaintiffs in this matter are relatively common among U.S. flight attendants in general.

3.5 Response to Dr. Scheinman's opinions

Dr. Scheinman espouses numerous medical opinions that are not supported by valid or sufficient evidence. These include her unsubstantiated claims about the frequency and results of Plaintiffs' skin patch testing; her conclusions about causation of Plaintiffs' claimed skin symptoms, hair loss, and respiratory complaints based on sparse, unvalidated, highly incomplete, and medically

unreliable or irrelevant information; and her inappropriate comparison of the frequency of self-reported skin complaints among Delta employees with the frequency of physician-reported occupational contact dermatitis in the United Kingdom. These problems are discussed in the following five subsections of my report.

3.5.1 Dr. Scheinman's claim that "many" Plaintiffs demonstrated "strong or extreme reactions" to the Uniforms upon skin patch testing is not substantiated. Dr. Scheinman reviewed relevant patch test results from only four Plaintiffs who apparently reported skin complaints.

Dr. Scheinman states in her report that "Many of the plaintiffs had strong or extreme reactions as seen objectively via patch testing to their actual Delta uniforms," yet this claim is not substantiated. A review of Dr. Scheinman's reliance materials reveals that she reviewed skin patch test results from seven Delta employees, including only four (REDACTED) who underwent patch testing to the Uniforms (summarized in Appendix C). An additional Plaintiff who underwent patch testing to other agents and is listed in Dr. Apple's reliance materials, but not Dr. Scheinman's, is also included in Appendix C. Of the four Plaintiffs with patch testing results for the Uniforms, three were reported to have a positive patch test result to one or more Uniform items, whereas one Plaintiff (REDACTED) was reported to have only negative patch test for the Uniforms. In the context of hundreds of Plaintiffs who reported one or more skin complaints (n = 723 with skin irritation and n = 669 with rash, per Dr. Freeman's summary of questionnaire data, as well as the "Quantitative Summary of Medical Injuries Related to Delta Uniforms" (Apple01770)), only three positive skin patch test results (4% of 723 or 669) constitute an insufficient basis for concluding that "many" Plaintiffs had strong or extreme reactions to patch testing with Uniform items.

Furthermore, Dr. Scheinman's statement that regarding "strong or extreme" skin patch test reactions is not supported by medical data. An "extreme" reaction on skin patch testing is considered to be a class 3 response. Of the four Plaintiffs who underwent skin patch testing to the Uniforms, only one (REDACTED) developed a class 3 reaction to Uniform items (Appendix C). However, this individual also developed class 3 responses to more than 20 other test substances, i.e., the majority of substances for which she was tested. These include substances that are common in many consumer products, including propylene glycol, 2-mercaptobenzothiazole, benzalkonium chloride, benzocaine, ylang-ylang oil, "fragrance mix," gold(i)sodium thiosulfate dihydrate, cobalt 11, formaldehyde, and other agents. None of the other Plaintiffs were shown in available medical records to have demonstrated an "extreme" (class 3) reaction to Uniform items. Dr. Scheinman provides no reliable basis upon which to make extrapolations from skin patch test results in a single Plaintiff to other Plaintiffs for whom no medical information is provide.

3.5.2 Dr. Scheinman fails to follow a proper scientific or medical diagnostic process in reaching the determination that Plaintiffs' skin symptoms and ongoing sensitivity were proximately caused by the Uniforms. In her deposition, Dr. Scheinman acknowledged that more medical information, which is lacking in her analysis, would be required to make such a determination for individual Plaintiffs.

Dr, Scheinman concludes in her report that "the dermatological symptoms or injuries, which include rashes, itching, hives, tingling, scarring, facial irritation, oozing and blisters, complained of by the Delta flight attendants were proximately caused by direct contact with uniforms."[15] She also concludes that Plaintiffs' "sensitization" was "proximately caused by Lands' End Uniforms." The basis for these causation opinions appears to be numerous complaints of skin symptoms among Delta flight attendants after they began wearing the Uniforms, laboratory garment testing results, and Dr. Scheinman's review of medical records selected by Plaintiffs' counsel.

Dr. Scheinman stated in her deposition that the occurrence of skin rashes in multiple Plaintiffs after wearing the Uniforms—that is, the "temporal connection between the exposure to the potential allergen and the onset of rashes"—was an important factor in her determination of causation for reported skin conditions (Deposition of Pamela Scheinman, p. 263). The issue of temporality, including the simultaneous self-reporting of exposures to Uniforms and the onset of skin symptoms, is discussed in section 3.4.1. Dr. Scheinman also testified that if a substantial proportion of the claimed symptoms were self-reported by a Plaintiff and not taken from medical records, then that would be a "fact of importance" to her (Deposition of Pamela Scheinman, p. 85). Indeed, she testified that if a large percentage of claimed symptoms were self-reported by Plaintiffs, she would "want to see validation by – you know, somebody else looking at it" (Deposition of Pamela Scheinman, p. 85).

Dr. Scheinman testified that she had no knowledge of how the list of Plaintiffs' claimed symptoms (i.e., the "Quantitative Summary of Medical Injuries Related to Delta Uniforms (created by counsel)," listed in her reliance materials) was obtained (Deposition of Pamela Scheinman, pp. 79–80). She also had no knowledge of whether the person(s) who compiled the list did so based on medical records or self-reported information (Deposition of Pamela Scheinman, p. 85). Yet, despite acknowledging the limitations of self-reported health symptoms and the need for validating such data, Dr. Scheinman made no attempt to validate Plaintiffs' self-reported symptoms by using the medical records that she received. When asked whether she

[15] In her deposition, Dr. Scheinman testified that she used the term "proximately caused" to mean "more likely than not" (Deposition of Pamela Scheinman, p. 125).

attempted to match up Plaintiffs' self-reported questionnaire data and their medical records, she replied: "I didn't make that attempt, no" (Deposition of Pamela Scheinman, p. 80).

In fact, given the exact correspondence between the numbers and proportions of Plaintiffs with various symptoms reported in the "Quantitative Summary of Medical Injuries Related to Delta Uniforms" (Apple01770–01771) and the numbers and proportions reported in Dr. Freeman's summary of health complaints among the 1,098 named Plaintiffs in the First Amended Complaint in this matter,[16] it is clear that the list of claimed injuries reviewed by Dr. Scheinman is based on the Complaint, not objective medical records. The Complaint also appears to be the source for Dr. Scheinman's statement in her report that "many of these employees complain of sensitization, which continues even after they are no longer wearing the uniforms."

Identifying and understanding the underlying sources of Plaintiffs' medical information is critical for determining whether a given exposure is responsible for causing any claimed health problems. Information sources are especially important in this matter, when the number of claimants appears to be substantially greater than the number of Delta employees who initially complained of Uniform-related health concerns. In their Health Hazard Evaluation of Uniform-related health complaints among Delta employees, NIOSH reported that by mid-May 2019, a full year after the garments were introduced to the workforce, there were 277 total health complaints among in-flight service personnel (NIOSH, 2019). According to Lands' End employee Ms. Kallie Sersch, flight attendants were responsible for 82% of complaints reported directly to Lands' End (Deposition of Kallie Sersch, pp. 20–21), and Table 5 of Dr Freeman's report shows that 91% of Plaintiffs who completed the symptom questionnaire were flight attendants. Thus, there appears to be a substantial discrepancy in numbers between the 277 Delta flight attendants who reported health concerns to NIOSH and the 908 Plaintiffs (predominantly flight attendants) who reported health complaints, including 723 who reported skin irritation alone, in the document reviewed by Dr. Scheinman.[17]

At the end her deposition, Dr. Scheinman acknowledged that she lacked sufficient information to make a causal determination connecting the Uniforms to claimed skin symptoms among Plaintiffs whose medical records she did not review. In particular, Dr. Scheinman was asked to set aside the approximately 16 Plaintiffs whose medical records she reviewed, and to answer the question of whether "[f]or everybody else who is a Delta employee who reported some skin symptoms, you do not currently have enough information to, for each one of those people individually, answer these questions, yes or no?" In response, she stated: "That's correct. Absolutely" (Deposition of Pamela Scheinman, pp. 270–271). Likewise, when asked, "But you

[16] Examples include 711 (65%) reporting fatigue, 723 (66%) reporting skin irritation, 669 (61%) reporting rash, 552 (50%) reporting itchiness, 249 (23%) reporting hives, 564 (51%) reporting headaches, 382 (35%) reporting anxiety, 249 (22%) reporting memory issues, 550 (50%) reporting coughing, 515 (47%) reporting breathing difficulties, etc.

[17] Quantitative Summary of Medical Injuries Related to Delta Uniforms (Apple01770)

don't have any information one way or the other about whether the uniforms were a contributing cause of skin rashes for any employees other than ones whose records you reviewed already?" Dr. Scheinman responded: "That's true. I mean I can only summarize, but yes. I can't – without seeing them, I can't – but it does seem suspicious. It seems like a smoking gun to me" (Deposition of Pamela Scheinman, p. 279).

3.5.3 Dr. Scheinman's opinion that complaints of hair loss among Plaintiffs were due to high levels of mercury and other heavy metals from the Uniforms is speculative, not based on a valid medical decision-making process, and not supported by objective garment testing data, medical evidence, or mercury toxicity data.

Alopecia, the medical term for hair loss, is a common complaint among Plaintiffs in this matter, including 34% of Plaintiffs according to the symptom questionnaire (Table 7 of Dr. Freeman's report) and 23% of Plaintiffs according to the "Quantitative Summary of Medical Injuries Related to Delta Uniforms" (Apple01770). In her report, Dr. Scheinman states that based on the analysis by Enthalpy Analytical,[18] "many" Uniforms contained "high amounts of heavy metals" including mercury, antimony, and chromium. She goes on to conclude, "Given the high levels of mercury and other heavy metals present in the uniforms and the wearing of uniforms for hours, it is more likely than not, that heavy metals in these uniforms were systemically absorbed and caused alopecia."

Dr. Scheinman did not assess the potential dose of mercury or any other metal that a Delta employee could have received from wearing Uniform items that she identified as having "high" metal levels. Dr. Scheinman also did not evaluate what dose or level of mercury exposure would be required to cause toxicity, particularly hair loss. Instead, Dr. Scheinman cites a review publication by Yu and colleagues concerning drug-induced causes of alopecia, in which the authors describe two cases of alopecia that were considered to be related to mercury and other metal exposure (Yu et al., 2013). Dr. Scheinman fails to identify why the two mercury-exposed patients described in this review have any clinical relevance to Delta employees who wore the Uniforms.

In fact, the patients described by Yu et al. (2013) have little clinical relevance to assess any anticipated health effects from wearing the Uniforms. One of the published case reports reviewed by Yu et al. (2013) involves a woman who presented with rash, myalgias, hair loss, and photosensitivity, and was subsequently found to have self-injected herself with liquid mercury in an effort to obtain workers' compensation benefits (French et al., 2011). The authors reported that even though this woman denied exposure to mercury, a radiographic survey of the

[18] Enthalpy Analytical report # 311031

extremities showed extensive subcutaneous mercury deposits in the foot and antecubital fossae, and a chest radiograph revealed evidence of mercury emboli. The other case identified by Yu et al. (2013) involves a 51-year-old man who developed perianal gangrene, a high fever, gastrointestinal and constitutional symptoms, skin rash, anemia, hair loss, peripheral neuropathy, and muscle atrophy after two weeks of using a topical traditional Chinese ointment to treat an anal fistula[19] (Wu et al., 2013). The ointment was found to contain lead tetraoxide, arsenic, and mercury.

These two cases are not clinically relevant to establishing causation between exposure to mercury in the Uniforms and the onset of alopecia. The exposure circumstances described in the published case reports are markedly different from those that could occur from wearing the Uniforms. The first case involves subcutaneous exposure resulting from injection of elemental mercury into the skin, and the second exposure involves application of a topic ointment to an anal fistula, which bypasses the normal protective skin barrier function. The concentration of mercury in the first patient's 24-hour urine sample was 1,030 µg/L (French et al. 2011), and that in the second patient's urine on hospital day 21 was 5.8 µg/L (Wu et al., 2013). Two ointments used by the second patient were found to contain 166,700 ppm lead and 24.5 ppm mercury, and 12,200 ppm lead and 12.5 mercury, respectively (Wu et al. 2013). Thus, the Yu et al. (2013) paper does not provide valid evidence to substantiate Dr. Scheinman's assertion that Plaintiffs' reports of alopecia are due to mercury toxicity from wearing the Uniforms.

Dr. Scheinman fails to identify any medical or scientific literature to substantiate that wearing Uniforms with the measured levels of extractable mercury (per Bureau Veritas) or total mercury (per ALS Environmental and Enthalpy Analytical) would result in mercury toxicity and/or alopecia. Instead, Dr. Scheinman appears to rely upon her interpretation that certain Uniform items had "high" levels of mercury and other heavy metals in comparison with OEKO-TEX® standards, and her belief that garments should not contain any mercury (Deposition of Pamela Scheinman, pp. 172–173).[20] As discussed in section 3.2, regulatory and industry standards, including OEKO-TEX® limit values, are not and cannot be interpreted as thresholds for toxicity or disease causation. Moreover, she fails to assess other potential causes for alopecia, a common condition in the general population with a wide variety of causes. In her deposition, Dr.

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[19] An anal fistula represents a tunnel or track between the skin surface and the underlying anal gland (Mayo Clinic, 2020d).

[20] "Q. And you mentioned heavy metals. Is there a -- I would assume that there are some dose or level of exposure to heavy metals that would be necessary before you would see symptoms; is that fair?
A. I'm not a toxicologist, but I mean I don't believe one should be wearing a garment with mercury in it.
…
Q. And you don't know -- as you just said, you don't know the dose or level of heavy metals within a garment that could potentially cause symptoms like hair loss, right?
A. I don't know the dose, but I mean I would -- again, I would say that's -- it would be I think pretty standard to say that I wouldn't want my family members or myself to be wearing a garment containing mercury or arsenic."

Scheinman acknowledged that all cases of alopecia cannot be assumed to be due to metal toxicity, since at least one type of alopecia, alopecia areata (an autoimmune disorder),[21] is "not felt to be … based on toxic metals in the bloodstream" (Deposition of Pamela Scheinman, p. 148).[22]

Alopecia has numerous potential causes: persons can acutely develop hair loss following multiple stressors such as recent medical illness, rapid weight loss, major surgery, recent childbirth, miscarriage, abortion, use of certain medications, a multitude of ongoing medical conditions, and toxicity associated with heavy metal exposures (Mubki et al., 2014a, 2014b; Shapiro et al., 2021). Yet, despite having virtually no objective medical information on alopecia from any Plaintiff, Dr. Scheinman made a broad determination that Plaintiffs' hair loss was caused by mercury exposure from Uniforms. A review of her reliance materials reveals no medical records for any persons who reported hair loss as a concern. Thus, Dr. Scheinman reached this causal determination without prior medical records, medical documentation of the presence of alopecia, or physical examination findings for even one of the hundreds of Plaintiffs apparently reporting alopecia. In her deposition, Dr. Scheinman acknowledged that additional clinical information beyond a simple self-report would be required to determine any individual person's underlying cause of alopecia (Deposition of Pamela Scheinman, p. 175).[23]

Dr. Scheinman readily could have performed a worst-case evaluation of potential mercury exposure to assess whether mercury from the Uniforms would be expected to cause alopecia or any other toxicity. For example, the amount of mercury contained in the Uniforms can be estimated by using the measured mercury concentration that Dr. Scheinman considered to be "high," multiplied by the expected weight of the garments.

From the Enthalpy report, the mercury concentrations that Dr. Scheinman considered to be "high" were 0.024 ppm in the ladies' blazer and 0.059 ppm in the ladies' pants. According to industry sources, the average weight of a ladies' blazer jacket is 230–400 grams and the average weight of ladies' pants is 300-400 grams.[24] Multiplying the reported concentration by the average weight of these garments results in a combined mercury content of 33.2 µg.

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[21] Plaintiff JA, for instance, was diagnosed with alopecia areata (Apple00091).

[22] Other types of alopecia, such as traction alopecia (caused by mechanical damage from repeatedly tension or pulling on hair) and tinea capitis (caused by fungal infection with ringworm of the scalp), also have widely accepted causes that do not include metal toxicity (Mubki 2014a, 2014b; Shapiro et al., 2021).

[23] "Q. So if somebody reported, I'm experiencing hair loss and you knew nothing more than that you wouldn't probably be able to tell that person much of anything about a medical cause, would you?

A. No."

[24] https://rocketmf.com/en/weight#tab-3

This amount of mercury would not be anticipated to cause any clinical effects, even if the mercury were in a more toxic form (i.e., methylmercury) than is present in garments,[25] and even if exposure were via ingestion, which results in substantially greater absorption of methylmercury than dermal contact (Broussard et al., 2002). A person who consumes a single serving of canned albacore tuna is exposed to a greater amount of mercury than would be experienced from ingesting both the blazer and dress.[26,] There is no reliable clinical evidence that eating one serving of canned tuna can cause alopecia or any other adverse health effects. Thus, if Dr. Scheinman had performed this basic comparison, she should have realized that her opinion on a causal relationship between dermal exposure to less-toxic mercury salts from the Uniforms and claimed alopecia in the Plaintiffs lacks face validity.

3.5.4 Dr. Scheinman's causation opinion that the proximate cause of Plaintiffs' respiratory complaints is off-gassing of formaldehyde or allergens is speculative and not supported by overall medical and scientific information on either exposure levels or diagnoses of respiratory outcomes.

Dr. Scheinman makes a causal determination for Plaintiffs' respiratory complaints without conducting a formal assessment of Plaintiffs' exposure potential, that is, an evaluation of whether off-gassing (i.e., airborne chemical releases) from the Uniforms could yield sufficient atmospheric levels of formaldehyde or allergens to cause the claimed respiratory symptoms. To support her conclusion that "respiratory symptoms or injuries including cough, breathing difficulty, chest tightness, and asthma, complained of by the Delta flight attendants were proximately caused by off-gassing of allergens and irritants from within the uniform," Dr. Scheinman states that several "very high readings" of formaldehyde exceeding 75 ppm were measured in Uniforms by TexTest (PLS-0063), and that formaldehyde is a "known irritant and allergen."

Here, Dr. Scheinman inappropriately uses an industry standard for formaldehyde that is designed to protect against skin effects through direct contact with formaldehyde, as opposed to respiratory effects from inhalation exposure to off-gassing formaldehyde. Specifically, Dr. Scheinman claims that the OEKO-TEX® standard for free formaldehyde is < 75 ppm, and that "a number of the Tex Test formaldehyde results exceeded this level." Besides inappropriately asserting that exceedance of an industry standard is indicative of increased health risk, Dr. Scheinman ignores that the basis for garment formaldehyde standards adopted in several

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[25] Methylmercury has greater toxicity potential than mercury salts, which are included as components of textile dyes (ATSDR, 1999; USEPA, 2002).

[26] A single 5-ounce (142-gram) serving of canned albacore white tuna contains approximately 50 µg mercury, based on an average mercury concentration of 0.35 µg/g (https://www.epa.gov/fish-tech/epa-fda-fish-advice-technical-information).

countries (e.g., Japan, Finland, France, New Zealand, and Norway), with limits set at 75 to 120 ppm, is the occurrence of contact dermatitis from direct skin contact (de Groot et al., 2010). By contrast, separate standards have been promulgated for formaldehyde in textiles not in direct skin contact. For example, the OEKO-TEX® limit value for formaldehyde in garments with close skin contact is 75 ppm, but that for garments without direct skin contact is 150 ppm (OEKO-TEX®, 2021). The American Apparel and Footwear Association uses the same guideline of 75 ppm formaldehyde for clothing in direct contact with skin for children and adults over 3 years of age, based on protection against contact dermatitis, but its guideline for textiles without direct skin contact is 300 ppm formaldehyde (AAFA, 2020). If off-gassing of formaldehyde from garments without direct skin contact were a principal health concern, then exposure limits for clothing without direct skin contact would be expected to be lower than those for clothing with direct skin contact, since emissions from clothes covering other garments would likely have a greater opportunity to reach the breathing zone than emissions from the covered garments (e.g., a dress covered by a coat). Dr. Scheinman provides no rationale for why she selected the formaldehyde standard for garments with direct skin contact to evaluate the toxicity potential for respiratory symptoms from inhalation exposure. Moreover, she provides no evidence that any formaldehyde garment standard, even that for clothing not in direct contact with skin, has relevance to respiratory toxicity.

Dr. Scheinman also appears to cherry-pick formaldehyde test results from a handful of garments that showed higher levels of formaldehyde, as opposed to numerous other test results showing levels that were non-detectable or well below the OEKO-TEX® Standard 100 limit value of 75 ppm for clothing in direct skin contact. These include 15 Uniform items tested for any or extractable formaldehyde by Bureau Veritas, more than 140 Uniform items tested for free and partially releasable formaldehyde by the Hohenstein Textile Testing Institute, and nearly 100 items tested for formaldehyde emissions by K Prime, as summarized in the Intertox report. Bureau Veritas did not detect any extractable formaldehyde in the Uniforms, and Hohenstein and K Prime reported no test results exceeding 75 ppm. By citing TexTest results for only seven (of 20) Uniform items with formaldehyde levels exceeding 75 ppm, Dr. Scheinman selectively relies on a small minority of results that she generalizes to all Plaintiffs to explain their respiratory symptoms. In contemporary U.S. garments treated with durable-press chemical finishes that release formaldehyde, the level of formaldehyde exposure is thought not to induce sensitization or elicit allergic contact dermatitis (de Groot and Maibach, 2010). With respect to potential allergens, which include a wide array of textile dyes, Dr. Scheinman presents no data supporting her assertion that any dye in a Uniform item would off-gas or result in an exposure level that would pose any health risk.

Besides lacking evidence of sufficient exposure, Dr. Scheinman's causation opinion is also flawed because she relies on very limited medical information concerning the underlying nature of the claimed respiratory symptoms. Despite having no objective medical information on the

vast majority of Plaintiffs, she assumes that the underlying medical causes of their claimed respiratory symptoms are actual respiratory disorders, rather that other, pre-existing medical conditions. Furthermore, she accepts that the results of Uniform challenge studies in two individuals provide evidence of pulmonary impairment, without assessing the validity of the test protocol or test findings.

Dr. Scheinman identifies two Plaintiffs, REDACTE and REDACTE, whom she describes as having developed respiratory compromise, as demonstrated by objective lung function tests during an inhalation challenge test. Dr. Scheinman also describes another Plaintiff, REDACTE, as having obtained an abnormal result on a bronchoprovocation test with methacholine. Dr. Scheinman apparently considers these three Plaintiffs' test results to constitute evidence that respiratory toxicity can occur from off-gassing of formaldehyde and allergens from the Uniforms.

However, Dr. Scheinman's causation determination for Plaintiffs' respiratory injuries is flawed and ultimately speculative. Non-specific respiratory symptoms, such as difficulty breathing and feeling short of breath, can be due to many underlying medical conditions that are not respiratory in nature, such as anxiety, anemia, cardiovascular disorder, deconditioning, obesity or even preoccupation with breathing (Mayo Clinic, 2020e). Yet, without examining relevant medical records, Dr. Scheinman implicitly assumes that all respiratory complaints among Plaintiffs are due to an underlying respiratory condition.

For several reasons, the reported challenge test results for two Plaintiffs, REDACTE and REDACTE, do not constitute reliable evidence to support a causal effect of emissions from Uniforms on claimed respiratory effects. First, the testing protocol was not standardized or validated. Second, the challenge test was not conducted in a blinded manner; that is, the patients apparently were aware that they were in close proximity to the Uniforms at the time of testing. Blinding is especially important when the measured endpoint is self-reported symptoms or tests that depend on a person's level of effort (e.g., spirometry, a test of lung function). Third, no measurements were made to ascertain that the specific Uniform items used in the challenge tests were releasing any specific chemical agents into the air or that they contained any detectable levels of certain chemical agents. Fourth, no control garments (i.e., visually similar garments without detectable levels of the chemicals of concern) were used to test for false-positive reactions. Finally, the actual breathing function test results were problematic, as explained further below.

In a review of 37 provocation studies involving a combined 784 persons who reported multiple chemical sensitivities, the authors concluded that such persons "do react to chemical challenges; however, these responses occur when they can discern differences between active and sham substances, suggesting that the mechanism of action is not specific to the chemical itself and might be related to expectations and prior beliefs" (Das-Munshi et al., 2006). Whereas the few adequately double-blinded studies generally showed no effect, poorly blinded or unblinded

studies (apparently such as those cited by Dr. Scheinman) were far more likely to elicit symptoms. Thus, the authors recognized that reported reactions to chemical exposures, including immunological, neurological, endocrine, and respiratory symptoms, may be due to psychophysiological mechanisms, rather than pathological or toxic processes.

Perhaps even more importantly, the results of the Plaintiffs' respiratory tests relied upon by Dr. Scheinman do not establish respiratory injury. One subject, REDACTE, is described by Dr. Scheinman as having experienced an 18% decrease in her forced expiratory volume in one second (FEV_1) after sitting next to her uniform for 2 hours. FEV_1 is a spirometry measure of how much air a person can exhale during a forced breath in one second. A decrease of FEV_1 following an inhalation challenge indicates that the airway is being obstructed, as might occur with an asthmatic or bronchospastic repose. Indeed, Dr. Scheinman apparently highlights the diminution of Plaintiff REDACTE's FEV_1 following this challenge as indicating that REDACTE had an asthma-like reaction to her uniform. However, interpretation of FEV_1 alone, without the context of other spirometry results, is not appropriate. In particular, the ratio of REDACTE's FEV_1 to forced vital capacity (FEV_1/FVC) remained normal at 100% of the predicted value (81%).[27] This result is unexpected if the true underlying cause of decreased FEV_1 is airway obstruction. On the contrary, a decrease in FEV_1 and FVC with maintenance of a normal FEV_1/FVC ratio is most consistent with not taking a deep breath, rather than any underlying airway obstruction. A diminished FEV_1/FVC ratio is considered to be a hallmark of airway obstruction. The American Thoracic Society and European Respiratory Society (ATS/ERC) authoritative guidance on lung function test interpretation highlights the concern over misdiagnosing airway obstruction or disease based upon a decrease in FEV_1 with a minimal change in FVC, noting: "Special attention must be paid when the FEV_1 and FVC are concomitantly decreased and the FEV_1/FVC ratio is normal or almost normal. This pattern most frequently reflects failure of the patient to inhale or exhale completely" (Pellegrino et al., 2005). This is precisely the type of change that REDACTE experienced after being in a room with her uniform for two hours. Thus, REDACTE's lung function test results do not demonstrate respiratory compromise, as claimed by Dr. Scheinman.

Plaintiff REDACTEI is reported by Dr. Scheinman to have experienced a 10% decrease in her FEV_1 after breathing for 60 minutes from a plastic bag that contained her uniform. Full spirometry results for REDACTE are not provided as part of Dr. Scheinman's reliance materials. However, a 10% drop in FEV_1 does not meet the ATS/ERC criterion for a "significant" change of 12% (Pellegrino et al., 2005). Any decrease in FEF_{25-75} (not quantified by Dr. Scheinman) is difficult to interpret without information on other test parameters, including FVC. Dr. Richard Hendershot notes that following the garment challenge, REDACTE exhibited vocal cord dysfunction, which he considered to be a positive test response. However, vocal cord dysfunction can be triggered by non-environmental causes such as anxiety, stress, and strong emotions (Cleveland Clinic, 2021). In

[27] Exhibit PLS0099

the absence of relevant information on REDACTE, medical history of asthma and other respiratory disorders, and the actual spirometry test results before and after the challenge, no reliable determination can be made whether she experienced a bronchospastic response following exposure to Uniform items.

The third Plaintiff identified by Dr. Scheinman as having evidence of respiratory disease caused by her Uniform is REDACTE, whom Dr. Scheinman describes as having been "diagnosed with having reactive airway disease, which only arose after she started wearing the uniform and when she went for a methacholine challenge. Three months after she stopped wearing the uniform, she no longer had a positive study and her breathing was much improved." Here Dr. Scheinman suggests that a positive methacholine challenge test provides evidence that REDACTE developed reactive lung disease caused by Uniform exposure, and that a subsequent negative methacholine challenge test provides evidence that REDACTE's reactive lung disease resolved after she was no longer exposed to the Uniform.

A methacholine challenge test is a standard bronchial provocation test with established protocols that is used to assess airway hyperresponsiveness. The test is used to establish a diagnosis of asthma especially when lung function tests are normal, during times when a person is asymptomatic. A methacholine challenge test is also useful to assess the severity of airway dysfunction in patients with asthma. The test involves the administration of progressively larger doses of inhaled methacholine, followed by spirometry testing. The test is discontinued when there is a drop of FEV_1 of 20% or more from baseline or the maximum dose of methacholine has been administered. A 20% decline in FEV_1 from baseline is considered to represent a positive test (Coates et al., 2017). The term PC20 is used to describe the provocative concentration of methacholine required to diminish the FEV_1 by 20%.

A review of REDACTE's methacholine challenge test results (Appendix D), however, reveals a highly unexpected finding. Although REDACTE's methacholine test report dated April 18, 2019, states that her test was positive with a PC20 of 4.3 milligrams, her actual lung function tests presented in the same report reveal that her FEV_1 never dropped by 20%, and thus her test was misinterpreted, assuming that no relevant test results are missing from the report. Specifically, her FEV_1 diminished by only 4% (from 3.07 L to 2.96 L), which represents a negative test finding. The technician who administered the spirometry test stated that no bronchodilator was given because REDACTE's test result did not show airway obstruction. If the spirometry test results shown in the report are accurate and not mislabeled, then the test interpretation of the reading physician (Charlton B. Strange, M.D.) is not supported by the actual test data. According to Dr. Scheinman, REDACTE underwent a subsequent methacholine test that was negative (medical records not provided; self-reported in Plaintiff questionnaire (Apple00006)). Overall, these test results provide insufficient evidence to conclude that REDACTE has or had reactive lung disease (a non-specific term) or asthma. Moreover, having two negative methacholine test results would make

a diagnosis of asthma unlikely. Even if [REDACTED]'s initial methacholine challenge test were positive, this result still would not establish an underlying cause of airway hyperresponsiveness, since false-positive test results are seen with other conditions such as allergic rhinitis and bronchitis (Sayeedi and Widrich, 2020).

In her deposition, Dr. Scheinman essentially acknowledged her lack of clinical expertise in respiratory disease and indicated that she would not be able to provide a causation opinion for many of Plaintiffs' claimed respiratory conditions and symptoms (Deposition of Pamela Scheinman, pp. 110–111).[28]

3.5.5 The frequency of skin complaints among Delta Above Wing employees cannot validly be compared, as done by Dr. Scheinman, with the estimated incidence of occupational contact dermatitis in the United Kingdom.

In support of her theory that the Uniforms caused skin symptoms, Dr. Scheinman compares the number of skin complaints among Delta employees to external data on occupational contact dermatitis. Quoting from the Intertox report, Dr. Scheinman notes that approximately 2.6% of Delta Above Wing employees filed health complaints between 2018 and 2019, and she estimates that if at least half of these complaints were skin-related, then approximately 1.3% of Delta Above Wing employees filed dermal complaints.[29] She then compares this figure with the estimated annual incidence of occupational contact dermatitis in the United Kingdom (0.013–0.034%) (Meyer et al., 2000; Turner et al., 2007), and states that the frequency of potential skin complaints among Delta Above Wing employees is "38–100 times published surveillance data on occupational contact dermatitis."

This comparison is not scientifically valid for several reasons, all of which inflate the rates of reported skin problems in the Delta employee population in comparison with the U.K. population used by Dr. Scheinman. First, according to the Complaint, the skin complaints reported by Plaintiffs and other Delta employees include a wide range of terms, such as "contact

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[28] "Q. But you would not -- if I asked you what is the most common cause of reactive airway disease you would say that that is not in your area of expertise?

A. Correct. However, if there was a garment that was next to a person that - and then it caused the reactive airway disease on two different occasions then I would say -- even without being an expert in pulmonary I'd say it appears that there's something in this garment that's causing reactive airway disease.

Q. Right. And I'm not asking you whether you might have reason to give that opinion in a particular circumstance. I'm asking more generally, do you consider yourself an expert in the various causes and relative likelihood of causes for pulmonary symptoms?

A. No, definitely not."

[29] According to the Intertox report (p. vii), based on data from Delta as of May 6, 2019, 1 per 26 inflight service personnel, 1 per 53 Red Coats, and 1 per 85 airport customer service personnel reported skin complaints.

dermatitis," "skin blisters," "skin rashes," "boils," "hives," "bruising," "eczema," "scarring," "hair loss," "hair follicle inflammation," "skin irritation," and "itchiness." These complaints do not necessarily correspond to occupational contact dermatitis (or even contact dermatitis in general). Dr. Scheinman does not establish that for all or even most of the Delta employee complaints, she was able to consider the seven diagnostic criteria for occupational contact dermatitis (Mathias, 1989) and confirm that at least four of the criteria were fulfilled in each case. Thus, her comparison between the broad, diverse category of skin complaints and the specific diagnosis of occupational contact dermatitis is scientifically inappropriate.

Second, the complaints among Plaintiffs and other Delta employees are self-reported and include conditions not formally diagnosed by a medical professional, whereas all of the cases of occupational contact dermatitis described in the studies cited by Dr. Scheinman were diagnosed by dermatologists or occupational physicians (Meyer et al., 2000; Turner et al., 2007). Few barriers exist to self-reporting a skin problem, whereas diagnosis with an occupational skin disease in the U.K. requires evaluation by a medical specialist, which in turn requires a patient first to decide to present to a general practitioner or occupational health service, and then for the patient to be referred to a dermatologist or occupational physician (Meyer et al., 2000; Turner et al., 2007).

Third, reporting of occupational skin diseases by dermatologists and occupational physicians in the U.K. is voluntary, not mandatory, and population coverage is incomplete. As noted by Turner et al. (2007), "there are eligible dermatologists who do not report (either by declining to participate in [the reporting network] or by signing up to the scheme but not returning any reporting cards)," and only 12% of the U.K. is estimated to have access to the services of an occupational physician, including 43% of workers in health and social services, but only 6% of the rest of industry (Turner et al., 2007). These gaps are expected to result in underascertainment of occupational skin diseases by the U.K. reporting network, whereas Plaintiffs in litigation may be more motivated to self-report health conditions due to the potential for compensation.

Finally, the comparison drawn by Dr. Scheinman is distorted by population differences in age, sex, and most likely other demographic factors that influence the occurrence or self-reporting of skin problems. According to Dr. Freeman's summary of the Plaintiffs' questionnaire data, 90% of respondents who reported any symptoms (not necessarily dermatological) were women, and the average age was 51.6 years. The U.K. data from 2002–2005 presented by Turner et al. (2007) also show that the majority of occupational contact dermatitis diagnoses were among women under age 50 years. However, women comprised the minority of the total working population in the U.K., with a gender employment gap of more than 18%, in the 1990s and early 2000s, when the studies cited by Dr. Scheinman were conducted (Azmat, 2015; Devine and

Foley, 2020). Therefore, based on the age and sex distribution alone, the occurrence of skin problems would be expected to be higher among Delta employees than in the U.K. labor force.

Of note, Turner et al. (2007) and Meyer et al. (2000) list numerous exposures other than chemicals in garments that dermatologists and occupational physicians identified as potentially having caused their patients' occupational contact dermatitis. These include workplace exposures that could have been encountered by above-wing and below-wing airline employees, including soaps and cleansers, fragrances and cosmetics, temperature/humidity, wet work, friction, rubber, latex, nickel, bleach, drugs, epoxies, resins, acrylics, glues and paints, cutting oils and coolants, petroleum products, foods, preservatives, biological substances, and other agents (Meyer et al., 2000; Turner et al., 2007). If known or unknown increases in these workplace exposures occurred during the same time period as the Uniforms were worn, they also could have contributed to an increased occurrence of skin complaints.

3.6 Response to Dr. Apple's opinions

Besides the problems shared with other Plaintiffs' health experts, Dr. Apple appears to incorrectly equate the presence of crocking with exposure to metals from garments, and he inappropriately assumes that the presence of any symptom that may be associated with metal exposure must have been caused by that exposure. Dr. Apple also disagrees with the generally accepted toxicological principle that every substance has a level, whether known or unknown, below which no discernible human health effect occurs. Instead, he espouses the opinion that the minimal toxic exposure level differs among individuals. As discussed below, however, this opinion is inconsistent with Dr. Apple's causal determinations for Plaintiffs in this matter, given that he reviewed partial medical records for only 22 Plaintiffs, and did not link individual-specific exposure information from Uniform items or biological testing to any of those 22 Plaintiffs. Dr. Apple's opinions on Plaintiffs' blood levels of heavy metals and antimony are also flawed and unsubstantiated, as discussed below.

3.6.1 Dr. Apple's approach to causation does not follow generally accepted medical or scientific methods, resulting in speculative and scientifically unsupported causation opinions that are fundamentally based on incomplete and misinterpreted exposure information and ignorance of dose.

Dr. Apple's causal determination, as described in his report, is based upon his consideration of the following factors:

- Test results showing crocking of Uniforms;

- Staining of flight attendants' clothing, skin, and personal items due to crocking from Uniforms;
- Test results showing metals and formaldehyde in Uniforms;
- The potential for metals and formaldehyde to cause toxic effects, including certain non-specific health symptoms or injuries;
- Reports of certain non-specific health symptoms or injuries in Delta flight attendants;
- Reported improvement or resolution of some symptoms after the removal of Uniforms.

Dr. Apple's causation methodology, however, suffers from a fundamentally invalid exposure determination, including reliance on an uninformative proxy for exposure to metals and failure to establish that Plaintiffs were sufficiently exposed to cause adverse health symptoms. Dr. Apple states in section 10 of his report and he testified during his deposition (Deposition of Dr. Fred Apple, p. 162) that the crocking of Uniforms was a significant factor in his evaluation of Plaintiff's claimed metal-related symptoms. However, the mere presence of crocking of a garment provides little data to substantiate exposure potential or that the amount of any chemicals transferred from crocking would be sufficient to cause toxicity. Moreover, as explained in section 3.3.5, metals in textiles are typically chemically bound to the dye or the fabric fiber, and therefore unavailable for release.

Vartest Laboratories conducted crocking tests on the Uniforms using a method called AATCC Test Method 8, developed by the American Association of Textile Chemists and Colorists (AATCC, 2016).[30] Table B4 in Appendix B summarizes the crocking test results for the Uniform items tested by Vartest Laboratories.[31] In accordance with AATCC Method 8, the Vartest results provide no data concerning the amount of dye that is transferred from the garment. That is, a crocking test score is not necessarily correlated with the amount of dye transferred. Moreover, the crocking test evaluates only the dye that can be rubbed off from the surface of a garment, and not of the entire composition of a garment. Finally, absent information on handling of a garment prior to its submission to a laboratory, substances transferred in a crocking test may represent environmental contaminants introduced after garment production at the factory. Dr. Apple provides no evidence to substantiate that the crocking test has any validity for determining the degree of dye transfer to human skin from wearing a garment, or that any substances transferred during crocking would contain any of the chemicals detected by tests (e.g., those performed by ALS Environmental) that measure total chemical levels from a

[30] Vartest Laboratories, File TERREL.A093020A-D, October 1, 2020 (Apple 01374)

[31] In his deposition on March 12, 2021, Dr. Peter Hauser testified that "from a textile chemical, performance standpoint, [he] had no concerns about the performance of the fabric or the presence of those elements being there" (Deposition of Peter Hauser, p. 308).

pre-digested garment sample. No correlation has been established between a gray scale rating and the amount of metal transferred, if any.

Contrary to Dr. Apple's assumption about the equivalence between crocking and exposure to metals, results from Vartest Laboratories do not reveal evidence of potentially toxic levels of metals in the material that was transferred from the Uniforms during crocking tests. Using energy-dispersive X-ray spectroscopy, Vartest Laboratories conducted analyses to determine the composition of the crocked material, and found that the principal elements associated with the Uniforms included fluorine, silicon, and magnesium. No metals except for magnesium—which does not even have a toxicological profile published by USEPA[32] or ATSDR[33]—were reported as being detected in any of the material that was rubbed off from the Uniforms.

Dr. Apple also appears to disregard the results of tests for colorfastness[34] performed on the Uniforms by Hohenstein Textile Testing Institute using the ISO 105-E01 method, in which garments are soaked in sweat solutions for a fixed time and under pressure to test for color retention (ISO, 2013).[35] Among 18 Uniform samples (mostly purple but also pink, red, lilac, and grey in color) submitted for colorfastness testing, only one, a purple wool-blend vest lining, did not pass the colorfastness test requirement (Table B3 in Appendix B). Hohenstein Textile Testing Institute evaluated the same Uniform items for extractable metals and a broad range of other agents, none of which exceeded OEKO-TEX® Standard 100 limit values, including in the one Uniform item that failed the colorfastness test (Table B3).

Beyond misinterpreting the crocking test results and ignoring the colorfastness test results, Dr. Apple fails to consider the potential dose of the chemicals of concern. Instead, Dr. Apple essentially assumes that the presence of a symptom that could potentially be associated with a certain chemical exposure is a key factor in establishing causation, i.e., that chemicals from Uniforms, regardless of dose, must be responsible for any potentially related symptoms reported in Plaintiffs (Deposition of Fred Apple, pp. 123–124).[36]

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[32] https://cfpub.epa.gov/ncea/iris/search/index.cfm?keyword=magnesium

[33] https://www.atsdr.cdc.gov/toxprofiledocs/index html

[34] In his deposition, Dr. Apple appeared not to distinguish between crocking and colorfastness and appeared to consider staining from any garment as being due to crocking (Deposition of Fred Apple, pp. 38–39, 56–57, 125). In my report, when referring to Dr. Apple's use of the term "crocking," I have assumed that he could be referring to test results for either crocking or colorfastness.

[35] Hohenstein Textile Testing Institute report # 20.0.06546 (Apple01270); Hohenstein also tested the Uniforms for colorfastness using simulated saliva.

[36] "Q. So how can you determine if an individual plaintiff was exposed with say Antimony?

This approach to causation determination lacks medical and scientific validity. As an analogy, alcohol can cause various adverse health effects such as gastrointestinal symptoms, liver disease, and central nervous system effects (e.g., headache, dizziness, slurred speech, unconsciousness), among others. However, the occurrence of a symptom such as a headache or dizziness in a person, even an individual with an underlying history of alcohol abuse or even a recent history of consuming alcoholic beverages, cannot reliably be assumed to be due to the toxic effects of alcohol. As explained in section 3.4.4, many exposures and underlying conditions can cause headache, dizziness, and the other symptoms reported by Plaintiffs in this matter. Therefore, in evaluating the potential causal role of alcohol exposure in the onset of a person's headache or dizziness, it is necessary to consider the amount and timing of alcohol ingested, as well as information on other risk factors and the prior medical history of headache and dizziness, before a causal determination can be made.

Dr. Apple has not established that any Plaintiff could have been exposed to any specific chemical from the Uniforms at a dose sufficient to cause any symptoms. Accepting the mere presence of a symptom as evidence that sufficient exposure occurred, as Dr. Apple has done, results in a situation where the symptoms become a basis for explaining themselves. This type of faulty logic, which entirely ignores the critical issue of dose, could be used to conclude that multitudes of exogenous and endogenous agents played a causal role in the subsequent appearance of any person's non-specific symptoms. Without consideration of dose, there is no scientific, evidence-based way to identify the probable cause of any health effect. Directly controverting well-established general principles of toxicology, however, Dr. Apple explicitly testified that he considers dose to be unimportant for the determination of causation (Deposition of Fred Apple, pp. 50–51).[37]

A. I think the symptomology in itself is representative and does a very good job of foundation scientifically that we knew and know that there are chemicals and metals found in these garments and individual flight attendants experienced symptoms related to wearing the uniforms.

Q. Are you saying that the system [*sic*; *recte*: symptom] is evidence of the exposure?

A. I'm saying the symptoms along with the knowledge that the uniforms do contain these compounds, these elements, these chemicals they correlate very well with what was observed and correlates with what's in the scientific and medical literature.

Q. Are you basing your causation opinion on correlation?

A. I'm basing my opinions on the facts that uniforms are found to have these metals and chemicals that these medicals and chemicals are well scientifically medically founded to cause all the symptomologies I described in my Rule 26 report as an example."

[37] "Q. So, would you agree that the question of whether a substance is harmful depends on the dose that a person takes?

A. No.

Q. What literature are you relying on for that?

A. As I've said I've written -- read hundreds of chapters and articles that do not rely on a dose response relationship to symptoms someone experiences when exposed to metals."

3.6.2 Dr. Apple's opinion that toxic chemical levels differ for each individual person, and that chemicals generally lack some level at which they do not cause toxicity, is not scientifically supported.

In his deposition, Dr. Apple disagreed with the statement that every substance has a level at which there would be no effect in humans (i.e., a NOAEL, although he does not use this term); in response, he replied, "I'd say probably that would not be the case" (Deposition of Fred Apple, p. 60). Instead he opined that for all substances at issue in this matter, the adverse effect level—that is the minimal dose at which a substance can cause a given health outcome (i.e., a LOAEL, although he does not use this term)—is different for each individual person (Deposition of Fred Apple, p. 63). He also stated that he would not necessarily agree with the statement in the Intertox report that "to determine whether an effect can occur as a result of a specific exposure, we need to examine the hazard associated with the chemical and whether that, combined with the exposure, is adequate to result in an adverse effect"; on the contrary, he suggested that this statement is not true for "the majority of heavy metals we're talking about" (Deposition of Fred Apple, pp. 79–80).

Dr. Apple's opinions on this topic deviate from accepted science, including basic toxicological principles. As summarized in sections 3.1.2 and 3.3.4, all of the chemicals allegedly at issue are commonly found in the general environment, including foods, drinking water, soil, ambient air, and/or regulated consumer products, at background levels that are accepted as not causing toxic health effects (USEPA, 1988, 1998a, 1998b, 1998c, 2002b, 2002c, 2002d, 2002e, 2004, 2005, 2006, 2010, 2020a; ATSDR, 1999a, 1999b, 2003, 2004a, 2005, 2007a, 2007b, 2008, 2012, 2019a, 2019b, 2020; NRC, 2010a, 2010b; FDA, 2020c; NIOSH, 2020; National Institutes of Health, 2020). Furthermore, in their published toxicological reviews, where available, USEPA and ATSDR identify quantitative NOAELs and LOAELs for each of these chemicals. These levels, in turn, provide the scientific basis for the derivation of protective regulatory standards that are set to protect public health, including sensitive populations, as discussed in section 3.2.

For example, USEPA sets protective Reference Concentrations and Reference Doses for these and other chemicals, thereby defining estimates of a continuous inhalation exposure and a daily oral exposure, respectively, "to the human population (including sensitive subgroups) that is *likely to be without an appreciable risk of deleterious effects during a lifetime*. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used" (USEPA, 2020b; emphasis added). Likewise, ATSDR sets protective Minimal Risk Levels for these and other chemicals, thereby quantifying estimates of "the daily human exposure to a hazardous substance that is *likely to be without appreciable risk of adverse non-cancer health effects over a specified duration of exposure*" (ATSDR, 2018; emphasis added).

These and other health and regulatory agencies' identification of NOAELs and LOAELs and their setting of protective exposure limits directly contradicts Dr. Apple's opinion that the chemicals at issue in this matter lack levels at which no adverse health effects would be observed. Incidentally, Dr. Apple testified in his deposition that he did not typically use Minimal Risk Levels in his field (Deposition of Fred Apple, p. 59). He also stated that he is "not really sure" whether he is an expert in dose-response relationships, and that he himself has "never carried out a dose response relationship study" (Deposition of Fred Apple, p. 55).

3.6.3 If Dr. Apple's claim of individual-specific toxicity levels were valid, then available evidence would be insufficient to establish general causation overall or specific causation for any Plaintiff in this matter.

Dr. Apple testified in his deposition, "What could be toxic to you isn't toxic to me so you have to treat every individual as to the scenario they're exposed to" (Deposition of Fred Apple, p. 48). He added that "there needs to be some minimal dose for that individual, but the minimal dose will vary from individual to individual" (Deposition of Fred Apple, p. 88). If adverse effect levels differ for each individual Plaintiff and must be evaluated based on each Plaintiff's individual exposure scenarios, as suggested by Dr. Apple, then general causation could not be established at a broad, overall level for all Plaintiffs.

Furthermore, Dr. Apple has not provided the individual-level information that he says is needed to evaluate causation. Plaintiffs' experts have not provided quantitative individual-level data on any Plaintiff's exposure or dose with respect to any chemical that can be linked to his or her own Uniform items, nor have Plaintiffs' experts considered validated health outcome data for the vast majority of Plaintiffs. Dr. Apple acknowledged, "All I have is information on the content that was measured by many laboratories from fabrics and sometimes there were blood samples measured or urine, but a specific dose I have no information on" (Deposition of Fred Apple, p. 98). He testified that other than reading partial "records of several of the people listed in [his report]," he did not have any objective medical information about possible alternative causes of the Plaintiffs' claimed symptoms, and he did not receive complete medical records for any Plaintiff (Deposition of Fred Apple, pp. 88–89, 100). Thus, Dr. Apple did not attempt to determine from medical records whether any Plaintiffs experienced their claimed symptoms prior to wearing the Uniforms, or whether they had documentation of prior underlying health conditions that could have caused the claimed symptoms.

Factors considered to be important in reaching a diagnosis of a condition related to chemical exposure, including taking a meticulous history, determining the nature and extent of the exposure (including by conducting analytical laboratory tests), and assessing clinical signs and symptoms, have not been provided for the Plaintiffs. Dr. Apple is not a medical doctor and lacks the training and experience to evaluate the clinical significance of the broad range of mostly

self-reported symptoms claimed by Plaintiffs (Deposition of Fred Apple, p. 15). His assessment of Plaintiffs in this matter therefore falls short of being able to establish a medical diagnosis for any Plaintiff or to identify any underlying cause of their claimed health conditions (Deposition of Fred Apple, p. 94).[38] As discussed in section 3.3.3, Dr. Apple also did not determine the representativeness of the Plaintiffs whose partial medical records and clinical laboratory test results he reviewed.

No Plaintiffs' experts, including Dr. Apple, have linked individual-level exposures with individual-level health outcomes among Plaintiffs in this matter. That is, for any given Plaintiff, Dr. Apple and other Plaintiffs' experts apparently have not matched laboratory test results showing chemicals levels in Plaintiffs' own Uniform garments or, alternatively, Plaintiffs' blood or urine levels of chemicals attributable to their Uniform items (as opposed to other potential sources), with medical records documenting health outcomes in those same individual Plaintiffs. Where garment lab reports do not specify the names of owners of each Uniform item, Plaintiffs' experts appear not to have asked counsel to provide this information to enable matching of Plaintiff-specific garment and health outcome data. Even absent any information on individual-specific chemical exposures, Dr. Apple lacks information on how frequently and for what duration of time any Plaintiff wore their Uniforms, and how any Plaintiff cared for, cleaned, or stored their Uniforms (Deposition of Fred Apple, pp. 103–104).

Thus, Dr. Apple fails to provide the information that he identifies as being necessary considerations for specific causation, including information on each Plaintiff's dose of each chemical of concern attributable to their Uniforms, as well as (in Dr. Apple's opinion) an understanding of every individual Plaintiff's particular susceptibility to each chemical. Consequently, Dr. Apple cannot establish that any Plaintiff's claimed symptoms or health conditions are due to exposure to metals or other chemicals from the Uniforms.

3.6.4 Dr. Apple's claim that Plaintiff's clinical laboratory tests revealed chemicals and heavy metals "at elevated and sometimes dangerous levels" is not substantiated.

Dr. Apple states in his report: "Review of various labs studies performed upon the 22 selected employees, further confirms that chemicals and heavy metals (also including arsenic #12 p287, lead #7 p207and [*sic*] copper #18 p584, not noted above) were found at elevated and sometimes dangerous levels and which coincide with the complaints of those employees shortly upon wearing the new Delta uniform." However, Dr. Apple provides no scientific or medical

[38] "Q. Are you offering a differential diagnosis opinion in this case?

A. No, my opinions are strictly based on the symptomology correlation with the different metals and toxins and chemicals found to be crocked from these materials and the symptomology of the individuals who wore them."

reference as a basis for concluding that chemicals or metals were present at "dangerous" levels in any Plaintiff.

For one of the Plaintiffs identified by Dr. Apple, his comparison of the test results with the laboratory reference range is simply incorrect. According to Plaintiff REDACT's laboratory report from Doctor's Data, Inc., her urine lead level of 8.8 µg/L on April 4, 2019, was outside the laboratory reference value of <2 µg/L.[39] However, Dr. Apple fails to recognize a critical aspect of this test result, namely, that the reported reference value is not applicable for this individual. The laboratory report states: "Reference intervals and corresponding graphs are representative of a healthy population under non-provoked conditions. Chelation (provocation) agents can increase urinary excretion of metals/elements." Thus, the reference value is applicable for urine tests that are collected under normal, non-provoked conditions. REDACT's laboratory report, however, notes that she was administered a provoking agent, dimercaptosuccinic acid (DMSA) at 500 mg, prior to the collection of her urine sample. DMSA is a chelating agent that increases the excretion of selected metals, including lead, from the body. Thus, Dr. Apple misapplied the laboratory reference range and misinterpreted REDACT's laboratory test result as indicating an elevated urinary lead level.

Of note, the use of post-provocation testing is considered unreliable for diagnostic purposes, and is described by the American College of Medical Toxicology as "fraught with many misunderstandings, pitfalls and risks" (ACMT, 2010). There is no standard, validated reference range for lead or many other metals measured in post-provocation urine, and failure to distinguish between post-provocation test results and non-provoked reference ranges can result in invalid clinical determinations (Ruha, 2013). Even healthy persons without metal toxicity can significantly increase urinary metal excretion following the administration of a chelating agent.

A second Plaintiff identified by Dr. Apple, Plaintiff REDACTE, had an undated blood arsenic level of 25 µg/L, which is outside the reported reference range of 2 to 23 µg/L.[40] However, Dr. Apple fails to mention that the laboratory report states, "Seafood consumption within 24 hours of collection can markedly elevate blood arsenic levels." Dietary intake of folate, which is found in fortified cereals and breads, legumes, and leafy green vegetables, as well as intake of grapes, wine, beer, rice, and other dietary sources, can also have a strong influence on blood arsenic levels, which are transient in nature and reflect recent exposures (ATSDR, 2007a; Bae et al., 2017). Absent a detailed dietary history—as well as arsenic speciation to determine the distribution of organic and inorganic arsenicals, which vary substantially in toxicity (ATSDR,

[39] Apple00207

[40] Apple00287

2007a), the arsenic blood test result for REDACTE is practically uninterpretable and of dubious clinical value.

Finally, the third Plaintiff identified by Dr. Apple as an example of an individual with "elevated and sometimes dangerous" metal levels is Plaintiff REDACTE, who Dr. Apple claims had an elevated level of copper. This claim, however, is not supported by laboratory test data. The test result for REDACTE referenced by Dr. Apple is not even a value for a copper level in blood, urine, or any other tissue; instead, it is a description of a patch test result for copper sulphate,[41] with no relevance for assessing REDACTE's biological dose of copper.

3.6.5 Dr. Apple lacks scientific and medical support for his speculative opinions that the Uniforms are responsible for increased blood antimony levels and, consequently, for claimed health symptoms in three Delta flight attendants. His evaluation fails to address technical limitations of the blood test, does not consider all of the Uniform testing data, ignores other potential sources of antimony, and disregards the issue of clinically significant dose.

During his deposition, Dr. Apple interpreted a blood antimony level reported in Exhibit 15 as being "increased" (Deposition of Fred Apple, p. 111),[42] which he attributed to contact with the Uniforms (Deposition of Fred Apple, p. 122). Dr. Apple also used blood antimony test results to validate the presence of symptoms among Plaintiffs (Deposition of Fred Apple, pp. 123–124), despite having no data to substantiate that antimony levels in the Uniforms exceeded relevant standards or would release a sufficient level of antimony to affect blood antimony levels or cause an adverse health effect, or that blood antimony levels in any Patient was at a level where any claimed symptoms or toxicity could occur.

Antimony is a metal that is found in the earth's crust and is used in a wide array of applications, including as a fire retardant (primarily as antimony trioxide) in textiles, plastics, rubber, adhesives, pigments, and paper (ATSDR, 2019a; PubChem, 2021b). Antimony is also found in a variety of foods, albeit at low levels, and used in medications to treat leishmaniasis.

Dr. Apple conducted only a cursory evaluation of the antimony content of the Uniforms, yet this information forms the basis of his opinion that the Uniforms are responsible for some of Plaintiffs' symptoms and "increased" antimony blood levels. As shown in Tables B1 and B2 in Appendix B, antimony was found not only in the current Uniforms, but also in the older uniforms designed by Richard Tyler and worn before May 2018. In fact, according to results

[41] Apple00584

[42] Apple00263

from ALS Environmental and Enthalpy Analytical, average antimony levels were higher in the older uniforms than in the current Uniforms. Moreover, Dr. Apple appears to have disregarded test results that revealed non-detectable levels of antimony in more than 100 Uniform items, as summarized in the Intertox report.

According to medical records, three Plaintiffs had blood antimony levels that were slightly above the testing laboratories' reference range: [redacted], 5.7 µg/L (reference range: < 5 µg/L, per the laboratory report) (NMS Labs, 2021)[43]; [redacted], 6.6 µg/L (reference range: ≤ 6.0 µg/L, per the laboratory report)[44,45]; and [redacted], 4 µg/L (reference range: 0–2 µg/L for "unexposed" persons and 3–10 µg/L for "exposed" persons, per the laboratory report) (Mayo Clinic Laboratories, 2020).[46] The Mayo Clinic Laboratories antimony reference ranges are based on studies that measured blood antimony levels in occupationally exposed workers, with a median blood antimony level of 10.1 µg/L (range: 0.5–17.9 µg/L) (Kentner et al., 1995); and in non-exposed residents of a community without high antimony levels in soil, with mean blood antimony level of 0.89 µg/L (range: 0.57–7.54 µg/L) (Gebel et al., 1998).

All of the testing laboratories caution that blood collection tubes can contain antimony from external sources, and use of specialized collection tubes is required to avoid the possibility of falsely elevated antimony test results due to contamination. Specifically, the laboratories that tested these three Plaintiffs' blood for antimony levels all specify that typical blood collection tubes with royal blue tops, which are commonly used for trace metal studies, cannot be used to test for antimony (Mayo Clinic Laboratories, 2020; ARUP Laboratories, 2021; NMS Labs, 2021). NMS Labs provides an additional disclaimer that "NMS Labs has demonstrated that certain collection tubes can artifactually increase measured antimony concentrations rendering reported concentrations difficult to interpret," and recommends that "unexpected elevated results be verified by testing another specimen" (NMS Labs, 2020).

The unique specimen collection requirements for antimony, as distinct from other metals, raise concerns about the validity of test results with values outside of the reference range, especially if the results are not validated. I did not see any evidence that any of the antimony tests for Plaintiffs [redacted], [redacted], or [redacted] were repeated or validated. I would expect that Dr. Apple would have made attempts to validate antimony test results upon which he was basing causation opinions. Misinterpretation of antimony levels biologically detected in firefighters led to a pseudo-outbreak of antimony toxicity that drew national media attention and resulted in discontinuance of some clothing (CDC, 2009). A detailed follow-up investigation by CDC,

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[43] Apple00263

[44] Apple00449

[45] ARUP Laboratories (2021) currently identifies the reference range for antimony as ≤ 3.0 µg/L (https://ltd.aruplab.com/Tests/Pub/0099007).

[46] Apple00300

including antimony testing in biospecimens collected by CDC, revealed no evidence of excessive antimony absorption, and the firefighters' non-specific complaints of fatigue, headache, muscle cramps, and joint pains were attributed by CDC to other etiologies unrelated to antimony (CDC, 2009).

Dr. Apple acknowledged in his deposition that disclosures about falsely elevated test results are made in laboratory reports for blood antimony, yet he did not undertake any efforts to ascertain whether the blood samples for these three Plaintiffs were collected in tubes that were free from possible antimony contamination (Deposition of Fred Apple, pp. 111–112).[47] Further, Dr. Apple provides no evidence that antimony blood levels measured in any Plaintiff, if accurate, was at a level that would be expected to result in toxicity.

As reported by Mayo Clinic Laboratories, the reference ranges are based on the potential for exposure, and not any type of toxicity parameter (Kentner et al., 1995; Gebel et al., 1998). NMS and ARUP do not cite the specific studies that form the basis for their reference ranges, but they do indicate that the purpose of the blood antimony test is to assess exposure. The three Plaintiffs' blood antimony test results, although greater than average or median levels, were within the range of blood antimony levels in a control population without any unusual source of antimony exposure (Gebel et al., 1998). Overall given the technical issues related to antimony testing and the occurrence of blood antimony levels that fall within the range of an unexposed reference population, along with the reported levels of antimony in the Uniforms as summarized by Intertox, Dr. Apple's conclusions about antimony exposure and claimed health effects among Plaintiffs lack medical and scientific validity.

[47] "Q. Do you know if -- do you know what type of collection tube was used for this analysis?
A. No, I do not.
Q. So you can't rule out that this an article officially [*sic*; *recte*: artificially] increased level?
A. These are standard comments that laboratories put on results of led [*sic*] testing so I think it would be difficult to determine whether or not that would have been a concern with this comment. It would require an investigation from that report to find out what type of blood tube - tube type it was whether it was a defined -- excuse me -- defined tube types of green top, purple top, a red top or blue top. That would clearly define whether or not this was a problematic tube type.
Q. You didn't investigate what tube type was used here?
A. No, I did not because most of the time this is I said a pretty standard comment used, but I did not investigate this."

4.0 Conclusions

Plaintiffs' experts' methodology for assessing both general and specific causation in this matter is fundamentally flawed. None of Plaintiffs' experts have quantified the amount of metals or other chemical agents that could be released from any of the Uniform items, even though this is a critical factor in determining the potential dose of any specific agent from dermal absorption or inhalation, and whether such a dose could result in toxicity. Moreover, Plaintiffs' experts have failed to consider and rule out the many potential alternative causes of the claimed health conditions. Instead, they appear to have made an a priori determination, without appropriate scientific or medical evidence, that the claimed health conditions were caused by chemicals in the Uniforms. This conclusion is based in part on Plaintiffs' experts' erroneous perception that the Uniforms did not meet OEKO-TEX® industry standards. In fact, Plaintiffs' experts fail to recognize that they misinterpreted test results relative to the standards, and that virtually all Uniform items met the relevant standards. Moreover, such standards are not an appropriate scientific basis upon which to assess general or specific causation, since they are not thresholds for toxicity. Plaintiffs' experts have not shown that any chemicals of concern in this matter were present in Uniforms at levels that have been demonstrated to cause the claimed health effects in general.

Because sensitized persons can react to much lower doses of chemical agents than the general population, it is plausible that individuals with underlying sensitivity to certain chemical agents could experience skin symptoms from the Uniforms and other garments. However, based upon the limited medical records available in this matter, Plaintiffs' experts have not presented or reviewed sufficient evidence to substantiate that any Plaintiffs experienced a hypersensitivity reaction to the Uniforms. Such a determination would be individual-specific, and would not be generalizable to all Plaintiffs, the large majority of whom would not be expected to have underlying sensitivity to any given agent. Moreover, Plaintiffs have not identified any persons who claim symptoms due to pre-existing hypersensitivity to chemicals in the Uniforms; instead, they appear to allege that the Uniforms caused new onset of sensitization-related symptoms.

Without having examined a single medical record to verify any health conditions (in the case of Dr. Freeman), or based on a review of partial medical records for fewer than 30 combined Plaintiffs (in the case of Dr. Scheinman and Dr. Apple), Plaintiffs' experts make specific causation determinations for approximately 1,000 Plaintiffs whose health claims they attribute to Uniform-related exposures. In doing so, Plaintiffs' experts fail to evaluate underlying medical and exposure histories that could explain the claimed health conditions. Moreover, they have not determined for any Plaintiffs whether any of the claimed health conditions could be verified in their medical records or clinical test results, or whether any of the tested Uniform items could be linked to a Plaintiff with a medical record.

In summary, Plaintiffs' experts have failed to satisfy key aspects that would be necessary to establish general and specific causation, as set forth by the Reference Manual on Scientific Evidence by the National Research Council and the Federal Judicial Center. Instead, Plaintiffs' experts' opinions, which purport to make causation determinations for approximately 1,000 Plaintiffs, are based upon unverified assumptions about exposure to chemicals in the Uniforms, misinterpretation of cherry-picked Uniform test results while ignoring the aggregate Uniform test findings, a small number of selected partial medical records for fewer than 30 Plaintiffs not known to be representative, misinterpretation of clinical laboratory test results for some chemicals found in the Uniforms, and self-reported, unvalidated questionnaire data on health symptoms. To suggest that Plaintiffs' experts' analysis, based on such insufficient and incomplete scientific and medical evidence, could reliably determine the underlying nature and causes of health conditions for any individual, not to mention 1,000 individuals, lacks face validity and challenges scientific credulity.

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